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# Systematic Literature Review on the Efficacy of Sofosbuvir–Daclatasvir With or Without Ribavirin in the Treatment of Hepatitis C

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**ABSTRACT**

Hepatitis C is a global infection that can lead to liver fibrosis, cirrhosis, and hepatocellular carcinoma. This study systematically evaluates the effectiveness of Sofosbuvir-Daclatasvir with or without Ribavirin using a Systematic Literature Review (SLR) approach following PRISMA guidelines. Database searches were conducted in the Cochrane Library and PubMed using predefined keywords, and eligible experimental or observational studies reporting SVR12 outcomes were included. Data screening, selection, and extraction were performed based on patient characteristics, treatment regimens, and outcome reporting. Analysis of six included studies shows consistently high treatment effectiveness, with SVR12 rates exceeding 90%. However, variations in response were observed in patients with advanced disease or comorbidities. The findings highlight strong overall efficacy but also emphasize the need for larger randomized clinical trials to validate these results and compare them with newer DAA regimens.



## INTRODUCTION

Hepatitis C is an infectious disease caused by the hepatitis C virus (HCV), significantly impacting global morbidity and mortality. HCV infection can lead to lidiver fibrosis, cirrhosis, and hepatocellular carcinoma (HCC), as well as an increased risk of death due to liver-related complications and cardiovascular diseases. Epidemiological data from 2015 estimate that 71 million people worldwide are infected with HCV, with a 1% global prevalence. The highest prevalence rates are found in the Eastern Mediterranean (2.3%) and Europe (1.5%), while in some countries, including Mongolia, Uzbekistan, Georgia, Egypt, and Gabon, the infection prevalence exceeds 4–6% (di Marco, L., la Mantia, C., & di Marco, V. (2022).. In Iran, the general population has a relatively low prevalence (0.5%), with a male-to-female ratio of approximately 10:1. Large-scale studies in Iran indicate a viremia rate of 0.3% among individuals over 40 years old (Merat, S., Sharifi, A. H., Poustchi, H., Hajiani, E., Gharavi, A., Karimi, J., Mansour-Ghanaei, F., Fattahi, M. R., Ahmadi, L., Somi, M. H., Kalantari, H., Ghadir, M. R., Sheikhesmaeili, F., Baniasadi, N., Sohrabi, M., Moosavy, S., Ziaee, M., Zahedi, M. J., Mokhtare, M., … Malekzadeh, R. (2020).

HCV infection is a bloodborne disease transmitted through direct contact with infected blood (e.g., transfusions) or indirectly via contaminated instruments (e.g., unsafe injections and unsterile medical procedures) (Mukhlis, 2025b; Mukhlis, Suradi, et al., 2023). Based on molecular diversity evolution rates, the virus is estimated to have been spreading for 500 to 2000 years, leading to its global distribution and establishing it as a major public health concern in many countries. Acute hepatitis C progresses to chronic infection in 70–80% of cases, significantly increasing the risk of complications such as cirrhosis and liver cancer (Roudot-Thoraval, F. (2020). Based on data from the Indonesian Ministry of Health, the prevalence of hepatitis C in Indonesia is around 1% or equivalent to 2.5 million people (Tirmizi, S. (2024, July 26). Kementerian Kesehatan Republik Indonesia.

(2023). This data is consistent with the results of the Basic Health Research Kementerian Kesehatan Republik Indonesia. (2023)., which showed a prevalence of the hepatitis C virus of 1.01%. However, the latest data on the prevalence of hepatitis C in Indonesia is still limited. The government continues to strive to conduct screenings in high-risk groups and provide Direct-Acting Antivirals (DAA) as part of the hepatitis C elimination strategy (Kementerian Kesehatan Republik Indonesia. (2023).

In response to the challenges posed by viral hepatitis, the World Health Assembly (WHA) approved the Global Health Sector Strategy on Viral Hepatitis 2016–2021 (GHSS-VH) in May 2016. The objective of this strategy is to eradicate hepatitis as a public health threat by 2030, aiming for a 90% reduction in incidence and a 65% decrease in mortality. It primarily focuses on hepatitis B and C due to their significant impact on global health and emphasizes the importance of universal access to prevention, harm reduction, blood safety, testing, and treatment. The GHSS-VH outlines five strategic directions—information, interventions, equity, financing, and innovation—to track progress toward the elimination of hepatitis (Cui, F., Blach, S., Manzengo Mingiedi, C., Gonzalez, M. A., Sabry Alaama, A., Mozalevskis, A., Séguy, N., Rewari, B. B., Chan, P. L., Le, L. vi, Doherty, M., Luhmann, N., Easterbrook, P., Dirac, M., de Martel, C., Nayagam, S., Hallett, T. B., Vickerman, P., Razavi, H., … Low-beer, D. (2023). In alignment with this strategy, the World Health Organization (WHO) has also set a goal to eliminate hepatitis C by 2030, which includes a 90% reduction in new chronic hepatitis C cases, a 65% reduction in mortality, and treatment for 80% of eligible individuals.

Despite these ambitious goals, significant challenges remain in achieving hepatitis C elimination (Mukhlis, Arifin, Ridwan, & Zulbaidah, 2025; Mukhlis, Arifin, Ridwan, Zulbaidah, et al., 2025). While the primary standard for hepatitis C treatment involves Direct-Acting Antivirals (DAAs), which inhibit viral replication by binding directly to replication complex components or terminating the RNA chain, treatment uptake has been insufficient to meet elimination targets. One of the most effective DAA combinations is daclatasvir (DCV) and sofosbuvir (SOF), with or without ribavirin (RBV) (Sacco, R., Messina, V., Gentilucci, U. V., Adinolfi, L. E., Ascione, A., Barbarini, G., Barlattani, A., Cariti, G., Cozzolongo, R., Fimiani, B., Francavilla, R., Furlan, C., Garrucciu, G., Iovinella, V., Rinaldi, L., Marignani, M., Begini, P., Palitti, V. P., Pellicelli, A. M., … Izzi, A. (2020). Hepatitis C treatment is life-saving, prevents transmission, and is cost-effective, with short-course, oral-only, safe, and well-tolerated regimens achieving cure rates of ≥95%. However, from 2014 to 2020, only 1.2 million people in the United States initiated treatment with DAA agents, falling short of national elimination targets. Treatment rates peaked in 2015 but declined to their lowest level by 2020, while 14,200 hepatitis C-related deaths were reported in 2019 (Thompson, W. W., Symum, H., Sandul, A., Gupta, N., Patel, P., Nelson, N., Mermin, J., & Wester, C. (2022).

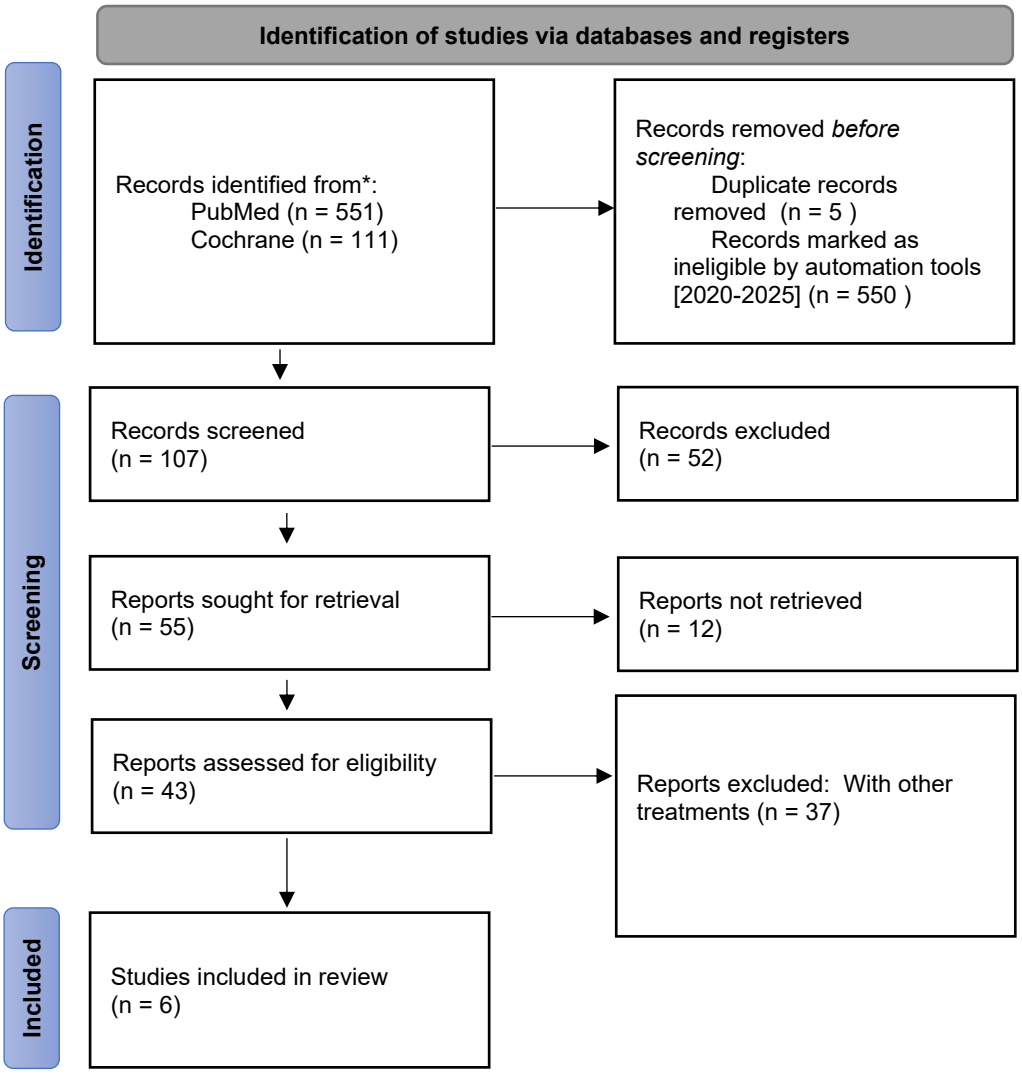
Despite the availability of multiple DAA regimens (such as ledipasvir–sofosbuvir, glecaprevir–pibrentasvir, and velpatasvir-based therapies), there remains a lack of consensus regarding the optimal regimen for diverse clinical settings, particularly in low- and middle-income countries where cost, accessibility, and genotype variability remain major constraints. Sofosbuvir–daclatasvir ± ribavirin offers several advantages, including pan-genotypic activity, shorter treatment duration, favorable safety profile, and significantly lower cost compared with other DAA combinations, making it especially relevant in resource-limited contexts. However, evidence comparing its effectiveness across different genotypes and patient subgroups (e.g., cirrhotic vs. non-cirrhotic) is still limited, especially in Southeast Asia. This gap underscores the need for more region-specific, real-world data to support optimal regimen selection.

Thus, the research gap in the current literature lies in the insufficient comparative and population-specific evidence supporting the use of Sofosbuvir–Daclatasvir ± Ribavirin over other DAA regimens, particularly within Indonesia and similar LMIC settings. This study addresses that gap by evaluating the clinical outcomes of this regimen in a real-world Indonesian population, thereby providing essential justification for its adoption in national hepatitis C elimination strategies.

## RESEARCH METHODS

This study is a Systematic Literature Review (SLR) conducted based on PRISMA guidelines, focusing on hepatitis C patients treated with sofosbuvir-daclatasvir with or without ribavirin. The

literature search was performed in PubMed and Cochrane, yielding a total of 662 articles (551 from PubMed and 111 from Cochrane). After the screening process, which included duplicate removal, title and abstract review, and full-text assessment, 6 studies met the inclusion criteria and were selected for analysis. The inclusion criteria for this study were (1) studies involving hepatitis C patients undergoing sofosbuvir-daclatasvir therapy with or without ribavirin, (2) studies evaluating treatment effectiveness based on cure rates and sustained virologic response (SVR), and (3) studies available in full-text format in PubMed and Cochrane. Meanwhile, the exclusion criteria included (1) studies that did not focus on sofosbuvir-daclatasvir therapy, (2) articles in the form of reviews, editorials, or case reports, and (3) studies with incomplete data or unclear methodology. The selected studies were analyzed based on cure rates and SVR to determine the effectiveness of sofosbuvir-daclatasvir treatment in hepatitis C patients.

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## RESULTS

### Table

| No | Author | Types of Research | Respondents and Research Location | Treatment Duration | Result |
|---|---|---|---|---|---|
| 1. | Sacco et | Retrospective, | 620 patients with chronic | 12 weeks (without | The research results show that 98% |

| | | | | | |
|---|---|---|---|---|---|
| | al., 2020 | multicenter, field-practice study design | Hepatitis C infection who have genotypes 1 to 4. The study was conducted in 21 centers spread across various regions of Italy. | cirrhosis or mild cirrhosis)<br>24 weeks (advanced cirrhosis or more severe clinical condition) | of the evaluated patients achieved SVR12, indicating a very high effectiveness of this treatment combination. Among patients with genotype 3, 98.8% achieved SVR12, while patients with genotypes 1 and 4 achieved SVR12 at 100%. Patients with genotype 2 achieved an SVR12 of 87.7%. |

| No | Author | Types of Research | Respondents and Research Location | Treatment Duration | Result |
|---|---|---|---|---|---|
| 2. | Butt et al., 2021 | Prospective observational | 300 patients aged over 12 years at Jinnah Postgraduate Medical Centre, Karachi | 12 weeks (without cirrhosis)<br>24 weeks (with cirrhosis) | The research results show that End of Treatment Response (ETR) was achieved by 97.33% of patients, while Sustained Virological Response (SVR) was achieved by 88.33% of patients. The highest SVR was found in patients with genotype 3, which was 97.9%, while the lowest was in genotype 4 at 54.5%. SVR in CHC patients reached 95%, in CC patients 88%, and in DCLD patients 92%. |
| 3. | Victor et al., 2022 | Prospective Cohort Study | 150 adult patients diagnosed with decompensated cirrhosis due to chronic HCV infection in two tertiary hospitals in Brazil | 12 weeks (mild cirrhosis)<br>24 weeks (severe cirrhosis) | Research results show that treatment with a combination of sofosbuvir and daclatasvir, with or without ribavirin, is effective in patients with decompensated cirrhosis due to HCV, with a virological success rate (SVR12) reaching 91% by intention-to-treat and 98.6% by per protocol. Common side effects include anemia (17%), mild renal dysfunction (14%), and infections (23%), particularly respiratory tract infections. |
| 4. | Hyppolito et al., 2024 | Retrospective observational (real-life study) | 1075 patients out of a total of 1522 registered in the state of Ceará, Brazil | 12 weeks | The research results show that the treatment of Hepatitis C using direct-acting antivirals (DAA) for 12 weeks successfully achieved a sustained virologic response (SVR) rate of 96.4%, with an overall cure rate of 96.5%. Serious side effects occurred in 3.5% of patients, mainly related to the use of ribavirin. This treatment has proven to be effective and relatively safe, but it requires special attention for patients with cirrhosis. |
| 5. | Sheikh et al., 2020 | Retrospective Cohort Study | 359 patients infected with Hepatitis C, divided into | 12 weeks with a follow-up period of up | The research results show that out of 86 patients who completed the |

| | | | | | |
|---|---|---|---|---|---|
| | | | 187 patients with cirrhosis and 172 patients without cirrhosis at Lahore General Hospital and Gambat Liver Transplant Center in Sindh, Pakistan. | to 45 weeks after treatment completion to evaluate SVR | follow-up, 81 patients (more than 94%) successfully achieved SVR. The effectiveness of the therapy significantly correlates with low platelet count, high bilirubin levels, and low albumin levels, while demographic factors such as gender, smoking, diabetes, alcohol, and Hepatitis B infection do not have a significant impact. |
| No | Author | Types of Research | Respondents and Research Location | Treatment Duration | Result |
| 6. | Merat et al., 2020 | Prospective Study | 1361 patients aged 12 to 75 years in Iran | 12 weeks (without cirrhosis)<br>24 minggu (with cirrhosis) | The research results show that the generic combination of Sofosbuvir-Daclatasvir has a high cure rate, with SVR12 reaching 94.7% (intention-to-treat) and 98.8% (per-protocol). Its effectiveness is consistent across all genotypes, including genotype 4 with a cure rate of 100%. The addition of Ribavirin does not provide a significant improvement. Most side effects are mild and only 2.4% of patients experience them. |

Table 1 Results

## DISCUSSION

Based on the analysis of six articles that satisfied the requirements for inclusion, the combination of Sofosbuvir (SOF) + Daclatasvir (DCV) with or without Ribavirin (RBV) has been proven highly effective in treating hepatitis C. Overall, this therapy achieved a Sustained Virological Response (SVR12) of over 90%, demonstrating its long-term ability to eliminate the virus. However, this high success rate needs to be interpreted carefully when compared with broader global evidence. Several international meta-analyses have shown that SVR12 for SOF + DCV ± RBV generally ranges from 92% to 98%, but substantial variability exists across regions, especially in low-resource settings, suggesting that contextual factors may influence treatment outcomes.

A study conducted by Sacco, R., Messina, V., Gentilucci, U. V., Adinolfi, L. E., Ascione, A., Barbarini, G., Barlattani, A., Cariti, G., Cozzolongo, R., Fimiani, B., Francavilla, R., Furlan, C., Garrucciu, G., Iovinella, V., Rinaldi, L., Marignani, M., Begini, P., Palitti, V. P., Pellicelli, A. M., … Izzi, A. (2020). examined 620 patients with various HCV genotypes (G1–4). The results showed that 98% of patients achieved SVR12, with the highest success rate in genotype 3 (98.8%) (Mukhlis et al., 2024; Mukhlis, Maryam, et al., 2023). This study confirmed that the SOF + DCV ± RBV combination is effective and safe, particularly for patients with harder-to-treat genotypes. Meanwhile, Merat, S., Sharifi, A. H., Poustchi, H., Hajiani, E., Gharavi, A., Karimi, J., Mansour-Ghanaei, F., Fattahi, M. R., Ahmadi, L., Somi, M. H., Kalantari, H., Ghadir, M. R., Sheikhesmaeili, F., Baniasadi, N., Sohrabi, M., Moosavy, S., Ziaee, M., Zahedi, M. J., Mokhtare, M., … Malekzadeh, R. (2020). , investigated the effectiveness of generic SOF + DCV in 1,361 patients and reported an SVR12 of 98.8%, with no significant difference compared to branded medications. This study highlighted that

generic drugs could be a more affordable solution, particularly for countries with limited economic resources.

In developing countries, a study by Butt, N., Akbar, A., Abbasi, A., Reema, S., Baqar, J. bin, & Shaikh, Q. H. (2019). conducted in Pakistan on 300 patients, including those with cirrhosis, showed an SVR12 of 88.33%, with higher effectiveness in patients without cirrhosis. This study indicated that while this therapy remains effective in patients with advanced liver disease, closer monitoring is required to ensure treatment success. Another study focusing on cirrhotic patients was conducted by Sheikh, N. T., Shaukat, M. T., Hussain, A., Ayyan, A., Iqbal, A., Karim, S., Ilyas, H., Ullah, K., Tahir, M. J., & Asghar, M. S. (2022). , involving 201 cirrhotic patients, where SVR12 reached 94.18%. However, patients with high bilirubin levels and low albumin levels exhibited lower treatment success rates.

Similar results were reported by Victor, L., Perez, R., Fernandes, F., Piedade, J., Villela-Nogueira, C. A., & Pereira, G. (2022). who studied 150 patients with decompensated cirrhosis in Brazil. Their findings showed that SVR12 reached 91%, but patients with cirrhosis were more prone to side effects, including anemia (17%), respiratory infections (29%), and kidney disorders (14%). These results confirmed that while therapy remains beneficial for patients with advanced cirrhosis, stricter monitoring is needed to manage potential side effects.

Beyond cirrhotic patients, the effectiveness of this therapy was also tested in patients with comorbidities such as HIV and liver transplantation. Hyppolito, E. B., Ramos, A. N., Teixeira, L. P., Bezerra, A. M., Mendes, L. A., Silva, T. L., Lima, J. M. de C., de Arruda, É. A. G., Guerra, E. J., Tavares, M. M. S., Lima, C. E. P., Esmeraldo, T. M., Pessoa, F. S. R. de P., Pierre, A. M. M., Pereira, K. B., Filho, A. H. A., Linhares, L. M. C., Ferreira, A. F., & Neto, R. da J. P. (2024). examined 1,075 hepatitis C patients in Brazil, including those with HIV and liver transplants, and reported an SVR12 of 96.4%. However, cirrhotic patients had lower success rates (93.4%) compared to non-cirrhotic patients (97.9%). These findings indicate that although patients with comorbidities can still achieve high treatment success rates, poorer liver conditions may reduce treatment efficacy. Therefore, closer monitoring is necessary for cirrhotic patients with comorbidities to ensure treatment effectiveness and safety.

The results of this systematic review align with several other studies that also evaluated the efficacy of SOF + DCV ± RBV. El-Kassas, M., Emadeldeen, M., Hassany, M., Esmat, G., Gomaa, A. A., El-Raey, F., Congly, S. E., Liu, H., & Lee, S. S. (2023). found that this therapy had a success rate of 95.3% in patients with advanced fibrosis, supporting the findings of Sacco, R., Messina, V., Gentilucci, U. V., Adinolfi, L. E., Ascione, A., Barbarini, G., Barlattani, A., Cariti, G., Cozzolongo, R., Fimiani, B., Francavilla, R., Furlan, C., Garrucciu, G., Iovinella, V., Rinaldi, L., Marignani, M., Begini, P., Palitti, V. P., Pellicelli, A. M., … Izzi, A. (2020). and Merat, S., Sharifi, A. H., Poustchi, H., Hajiani, E., Gharavi, A., Karimi, J., Mansour-Ghanaei, F., Fattahi, M. R., Ahmadi, L., Somi, M. H., Kalantari, H., Ghadir, M. R., Sheikhesmaeili, F., Baniasadi, N., Sohrabi, M., Moosavy, S., Ziaee, M., Zahedi, M. J., Mokhtare, M., … Malekzadeh, R. (2020). However, some studies have reported differences in effectiveness depending on patient conditions. Margusino-Framiñán, L., Cid-Silva, P., Rotea-Salvo, S., Mena-De-Cea, Á., Suárez-López, F., Vázquez-Rodríguez, P., Delgado-Blanco, M., Sanclaudio-Luhia, A. I., Martín-Herranz, I., & Castro-Iglesias, Á. (2020). Effectiveness and safety of sofosbuvir/velpatasvir ± ribavirin vs glecaprevir/pibrentasvir in genotype 3 hepatitis C virus infected patients. European Journal of Hospital Pharmacy, 27(1 e), E41–E47. https://doi.org/10.1136/ejhpharm-2019-002060reported that SVR12 was lower in patients with advanced fibrosis (85%), differing from Victor, L., Perez, R., Fernandes, F., Piedade, J., Villela-Nogueira, C. A., & Pereira, G. (2022)., who reported an SVR of 91% in cirrhotic patients. This suggests that fibrosis levels and liver conditions play a crucial role in treatment success, emphasizing the need for a more individualized treatment strategy.

The high effectiveness of this combination therapy can be explained by the mechanisms of the drugs involved (Mukhlis, Janwari, et al., 2023; Mukhlis & Abdullah, 2025). Sofosbuvir (SOF) is an NS5B polymerase inhibitor that works by blocking HCV RNA replication, preventing the virus from multiplying in the body. Daclatasvir (DCV) is an NS5A inhibitor, which disrupts viral

assembly and replication, effectively interfering with the overall viral life cycle. Some studies suggest that Ribavirin (RBV) works by increasing viral RNA mutations, but its effect is weaker compared to other Direct-Acting Antivirals (DAAs). Thus, Ribavirin is only recommended in specific cases, particularly for patients with cirrhosis or difficult-to-treat genotypes. The combination of these mechanisms explains why SOF + DCV ± RBV achieves a high viral eradication rate across diverse patient populations.

Despite the proven effectiveness of Sofosbuvir + Daclatasvir ± Ribavirin in treating hepatitis C, some limitations must be considered. Most studies are observational or retrospective, meaning their evidence strength is lower compared to randomized controlled trials (RCTs). Additionally, limited data on long-term effects, particularly in patients with advanced cirrhosis or kidney impairment, remains a challenge in implementing this therapy. Access to treatment also remains an issue, especially in developing countries, due to the relatively high cost of these drugs. Furthermore, the lack of studies on HCV genotype 6 highlights the need for further research.

To address these limitations, larger sample sizes are required for randomised controlled trials (RCTs), particularly for patients with severe cirrhosis and other comorbidities. Additionally, long-term safety studies should be conducted to understand the impact of this therapy on liver and kidney function. Evaluating treatment access policies in developing countries is also essential, given that generic drugs have proven effective at a lower cost. Lastly, further studies on HCV genotype 6 are needed to obtain comprehensive data on the effectiveness of this therapy in specific populations.

In conclusion, the combination of Sofosbuvir + Daclatasvir with or without Ribavirin is a highly effective therapy for hepatitis C, with an average SVR12 above 90% (Mukhlis, 2025a; Mukhlis & Saidah, 2025). However, treatment effectiveness may vary based on viral genotype, cirrhosis severity, and comorbidities such as HIV or liver transplantation. Therefore, closer monitoring and further research are still required to ensure long-term treatment success and expand access to this therapy across diverse patient populations.

## CONCLUSION

Based on the results of a systematic literature review, the combination of Sofosbuvir (SOF) and Daclatasvir (DCV) with or without Ribavirin (RBV) has proven to be very effective in the treatment of Hepatitis C, with a Sustained Virological Response (SVR12) rate consistently above 90%. The effectiveness of this therapy applies to various HCV genotypes as well as to patients with and without cirrhosis, although patients with worse liver conditions show slightly lower responses. The use of Ribavirin does not provide a significant increase in treatment success rates, except in certain conditions such as patients with advanced cirrhosis or difficult-to-treat genotypes. The side effects of this therapy are generally mild to moderate, with some cases of anemia, kidney dysfunction, and infections, especially in patients with more severe liver conditions.

These findings support the use of the SOF + DCV combination as the standard treatment for Hepatitis C, including in developing countries with limited access and resources. This therapy is not only effective but also safe for various patient groups, including those with comorbidities such as HIV and liver transplants. Overall, the combination of Sofosbuvir and Daclatasvir with or without Ribavirin can be an efficient and affordable solution to support the global elimination of Hepatitis C in line with the WHO target by 2030.

However, this review also highlights several limitations. Most included studies were conducted in specific geographic regions, which may limit the generalizability of the findings to broader populations. Variations in study design, sample sizes, and follow-up durations may also influence the consistency of reported outcomes. In addition, data on long-term safety—particularly regarding renal function, drug resistance, and post-treatment relapse—remain limited.

Therefore, further research is needed not only to evaluate long-term effectiveness and safety, but also to address gaps in evidence for special populations such as patients with decompensated cirrhosis, pediatric patients, and those with multiple comorbidities. Moreover, policy-level strategies—including pricing negotiations, expanded generic licensing, and national treatment

subsidies—are essential to enhance equitable access to SOF + DCV therapy in low- and middle-income countries.

## CONFLICT OF INTEREST

The authors declares that there is no conflict of interest.

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