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Research Letter

Real-world Effectiveness and Safety of Coblopasvir plus Sofosbuvir in the Treatment of Chronic Hepatitis C Infection in Wenzhou, Eastern China: A Multicenter Observational Study

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Hepatitis C virus (HCV) is primarily transmitted through parenteral exposure to infectious blood or body fluids.[1] If left untreated, chronic HCV infection can progress to cirrhosis and hepatocellular carcinoma (HCC), posing a substantial burden on individuals and healthcare systems.[2] In China, an estimated 10 million people bear a heavy burden of HCV disease (pooled prevalence of 0.91%), which remains one of the leading causes of HCC in China.[3,4] The development of direct-acting antivirals (DAAs) has offered high sustained virological response (SVR) rates and simplified treatment.[5]

Coblopasvir is a pan-genotypic inhibitor targeting the HCV nonstructural protein 5A. It has been approved in China for treating HCV across genotypes when combined with sofosbuvir, an NS5B polymerase inhibitor.[6,7] The top five genotypes in Mainland China are 1b, 2a, 3b, 6a, and 3a. Genotype 3b, in particular, is less likely to achieve an SVR compared to other genotypes.[8] Therefore, robust, region-specific effectiveness data on DAAs are crucial to guiding local treatment and accelerating HCV elimination as a public health threat. The effectiveness of the coblopasvir plus sofosbuvir regimen in treating different HCV genotypes and comorbidities in Eastern China requires further investigation.

This retrospective observational study aimed to evaluate the effectiveness and safety of the coblopasvir plus sofosbuvir regimen in a real-world setting among HCV patients with various genotypes (especially genotype 3b), cirrhosis, HCC, HBV co-infection, or HIV co-infection at three liver disease centers in Wenzhou City, Zhejiang Province, Eastern China (The Third Affiliated Hospital of Wenzhou Medical University, Pingyang People's Hospital, and Yueqing People's Hospital) from June 2023 to October 2024.

Participants with a diagnosis of chronic HCV infection based on the Guideline for the Prevention and Treatment of Hepatitis C (2022 version) in China were included. Eligible participants received a once-daily capsule of coblopasvir (60 mg) combined with a tablet of sofosbuvir (400 mg) (Beijing Kawin Technology Share-Holding Co. Ltd., Beijing, China) for 12 weeks. Based on clinical judgment, patients with genotype 3 or cirrhosis received concomitant ribavirin, which was administered twice daily with meals (400–1,000 mg/day for patients weighing <75 kg, 1,200 mg/day for those ≥75 kg, and an initial dose of 600 mg/day for patients with Child–Pugh class B or C).

All enrolled patients completed baseline, end of treatment (EOT), and 12 weeks post-EOT assessments. The data included demographic and clinical characteristics (comorbidities and concomitant medications), hematological (hemoglobin, platelet count, and white blood cell count) and biochemical (alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transpeptidase, albumin, alkaline phosphatase, creatinine, total bilirubin, glucose) tests, HCV antibody, HCV RNA, HCV genotype, HIV antibody, hepatitis B surface antigen testing, and liver imaging (liver stiffness measurement by FibroScan /ultrasound /computed tomography /magnetic resonance imaging).

The primary effectiveness endpoint was SVR12 rate, defined as the proportion of patients with HCV RNA < 15 IU/mL at 12 weeks after EOT. Secondary effectiveness endpoints included changes in liver function (albumin–bilirubin (ALBI) score) and fibrosis (Fibrosis-4 index, FIB-4, and aspartate aminotransferase-to-platelet ratio index, APRI) at

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Table 1. Baseline characteristics of the HCV-infected patients treated with the coblopasvir plus sofosbuvir regimen in Wenzhou, Eastern China

	***N* = 113**
Age, yr	46 (43–49)
Gender	
Male	95 (84%)
Female	18 (16%)
BMI, kg/m^2	23.0 (20.8–26.0)
HCV genotype	
1	17 (15%)
1a	2 (2%)
1b	15 (13%)
2	4 (4%)
2a	4 (4%)
3	65 (58%)
3a	35 (31%)
3b	30 (27%)
6	23 (20%)
6a	23 (20%)
Genotype uncertain	4 (4%)
HCV RNA titer, IU/mL	670,000 (94,000–3,500,000)
Co-infection	
HBV	10 (9%)
HIV	1 (1%)
Liver comorbidities	
HCC	1 (1%)
Compensated cirrhosis	17 (15%)
Other comorbidities	
Hypertension	10 (9%)
Diabetes	19 (17%)
Ribavirin	14 (12%)
Laboratory tests	
ALT (IU/L)	72.0 (40.0–109.0)
AST (IU/L)	56.0 (35.0–92.0)
ALP (IU/L)	82.0 (66.0–101.0)
GGT (IU/L)	82.0 (47.0–151.0)
ALB (g/L)	43.0 (41.2–45.9)
TBIL (μmol/L)	16.1 (12.1–21.7)
WBC (×10^9/L)	5.7 (4.6–6.9)
Hb (g/L)	157.0 (140.0–166.0)
PLT (×10^9/L)	172.0 (149.0–209.0)
Assessment index	
ALBI	−2.88 (−3.11 to −2.64)
FIB-4	1.84 (1.22–2.66)
FIB-4>3.25	17 (15%)
APRI	0.77 (0.47–1.42)
APRI>2	19 (17%)

ALB, albumin; ALBI, albumin–bilirubin; ALP, alkaline phosphatase; ALT, alanine aminotransferase; APRI, AST-to-Platelet Ratio Index; AST, aspartate aminotransferase; BMI, body mass index; FIB-4, Fibrosis-4 index; GGT, gamma-glutamyl transpeptidase; Hb, hemoglobin; HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HCV, hepatitis C virus; HIV, human immunodeficiency virus; PLT, platelet count; TBIL, total bilirubin; WBC, white blood cell count.

EOT and 12 weeks after EOT compared to baseline. Safety endpoints included the incidence of adverse events (AEs) of grade 3–5 and the proportion of patients who discontinued or interrupted treatment due to AEs among those receiving at least one dose of coblopasvir plus sofosbuvir. Other detailed information on methods is provided in Supplementary File 1.

A total of 147 patients with chronic hepatitis C were screened across three liver disease centers. Twenty-three patients were excluded due to active or past malignant tumors, severe cardiopulmonary insufficiency, ongoing antiviral therapy, or history of organ transplantation. After excluding 11 patients who were lost to follow-up (moving out, participating in another trial, or lost contact), 113 patients were enrolled (Supplementary Fig. 1).

Baseline data are presented in Table 1. The median age of the 113 participants was 46 years (*IQR*: 43–49), with 95 males (84%). The median BMI was 23.0 kg/m^2 (*IQR*: 20.8–26.0). The HCV genotypes were mainly genotype 3 (n = 65, 58%) and genotype 6 (n = 23, 20%). Ten patients had co-infection with HBV, and one with HIV. One patient had HCC, and 17 (15%; 12 male and 5 female) had compensated cirrhosis. Additionally, 10 patients had hypertension, and 19 had diabetes. At baseline, median ALBI was −2.88, and median FIB-4 and APRI were 1.84 and 0.77, respectively. Fourteen patients (12%; 11 with genotype 3b, two with genotype 3a and cirrhosis, and one with genotype 2a and cirrhosis) received ribavirin.

The overall SVR12 rate was 99.1% (112/113) (Table 2). The SVR12 rates with or without ribavirin were 100% (14/14) and 99.0% (98/99) (p = 0.694). SVR12 was 100% in patients with 1a, 2a, 3a, 3b, 6a, and undetermined genotypes (2/2, 4/4, 35/35, 30/30, 23/23, and 4/4, respectively). The SVR12 rate was 93.3% (14/15) in genotype 1b. For 10 patients co-infected with HBV, nine achieved SVR.

Compared to baseline, ALBI scores at EOT and 12 weeks after EOT were significantly lower (both −2.95 vs. −2.88, $p < 0.05$). In the compensated cirrhosis subgroup, similar results were observed (both $p < 0.05$). FIB-4 was significantly lower at EOT (1.11 vs. 1.84, $p < 0.001$) and 12 weeks after EOT (0.76 vs. 1.84, $p < 0.001$) than at baseline. Similarly, APRI scores decreased significantly (0.27 vs. 0.77 and 0.21 vs. 0.77, both $p < 0.001$) compared with baseline (Fig. 1). Among patients, no serious AEs were reported. The most common AEs during treatment were headache, nausea, fatigue, upper respiratory tract infection, and toothache (Supplementary Table 1).

One patient did not achieve a virological response at week 12 of treatment, as HCV RNA remained detectable despite completing the full 12-week course of antiviral therapy. He was a 45-year-old male with a BMI of 17.6 kg/m^2, genotype 1b, HBV co-infection, and an ALBI score of −3.12. He was treated with coblopasvir plus sofosbuvir without ribavirin. His

Table 2. SVR12 rate by subgroups in HCV-infected patients treated with the coblopasvir plus sofosbuvir regimen in Wenzhou, Eastern China

	SVR12 (N = 113)
Overall SVR12	112/113 (99.1%)
Genotype	
1a	2/2 (100%)
1b	14/15 (93.3%)
2a	4/4 (100%)
3a	35/35 (100%)
3b	30/30 (100%)
6a	23/23 (100%)
uncertain	4/4 (100%)
Comorbidities	
HCC	1/1 (100%)
Compensated cirrhosis	17/17 (100%)
HBV	9/10 (90.0%)
HIV	1/1 (100%)
Hypertension	10/10 (100%)
Diabetes	19/19 (100%)

HBV, hepatitis B virus; HCC, hepatocellular carcinoma; HIV, human immunodeficiency virus; SVR, sustained virological response.

baseline HCV RNA was 10,000 IU/mL, which increased to 12,000 IU/mL at week 12 of treatment. He was later switched to another DAA regimen and remains under follow-up.

This retrospective cohort study presented high SVR12 rates (99.1%) among HCV patients in Eastern China, including those with genotype 3b, cirrhosis, HCC, HBV or HIV co-infection, hypertension, or diabetes. In terms of safety, no patients discontinued or interrupted treatment due to AEs, and no serious AEs were reported. China has a large HCV-infected population with significant regional differences in genotype distribution.[9] Thus, there is an urgent need for a simple, pan-genotypic, all-oral regimen.[6] A phase 3 trial of coblopasvir plus sofosbuvir demonstrated an SVR12 rate of 97%.[7] To achieve the goal of eliminating the public health threat of hepatitis C by 2030, a simple and efficient pan-genotypic regimen is essential.[10,11]

The SVR12 rate in our study exceeded 99% compared with a reported 96% SVR12 rate for the sofosbuvir/velpatasvir regimen.[12] This difference is likely explained by the higher effectiveness of the coblopasvir plus sofosbuvir regimen demonstrated in patients with genotype 3b, a subtype in which sofosbuvir/velpatasvir showed lower effectiveness (76%) in the randomized controlled trial. Genotype 3b is considered less responsive to antiviral therapy and is recognized as a negative prognostic marker.[13] In Northern China, genotypes 1 and 2 are predominant, while in Eastern China, such as Zhejiang Province, genotype distribution is more diverse.[14] We further analyzed SVR12 outcomes in genotype 3 patients. In our study, the SVR12 rate was 100% in both genotypes 3a (35/35) and 3b (30/30), which was higher than the 83% (49/59) SVR12 rate reported for sofosbuvir/velpatasvir in the Chinese population.[12] The coblopasvir plus sofosbuvir regimen represents slightly higher effectiveness, given its 100% effectiveness in 30 patients with genotype 3b. This makes it a critical tool in public health strategies to achieve hepatitis C elimination.[15]

This study also observed improvements in liver function

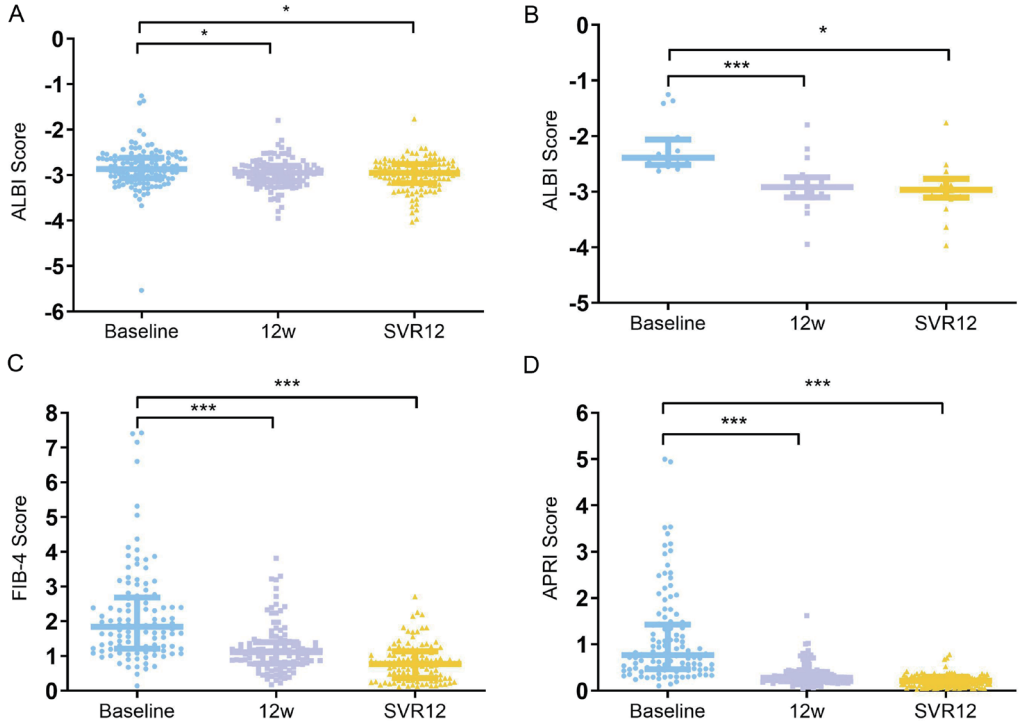

Fig. 1. Changes in ALBI scores in the total population (A), the patients with cirrhosis (B), FIB-4 (C), and APRI (D) at treatment baseline, EOT, and 12 weeks post-EOT in HCV-infected patients treated with the coblopasvir plus sofosbuvir regimen in Wenzhou, Eastern China. ALBI, albumin–bilirubin score; APRI, AST-to-platelet ratio index; EOT, end of treatment; FIB-4, Fibrosis-4 index; SVR, sustained virological response. Note: *$p < 0.05$, ***$p < 0.01$.

and alleviation of liver fibrosis following treatment, as shown by significant reductions in ALBI, FIB-4, and APRI scores from baseline to EOT. Similar findings have been reported with the sofosbuvir/velpatasvir regimen.

This study has several limitations. First, due to the extremely low prevalence of HCV genotypes 4 and 5 in China and the small sample size in subgroups of HBV co-infection or HIV co-infection, treatment outcomes in these subgroups may not have been adequately assessed. Second, this study is a retrospective observational study, and 11 patients were lost to follow-up due to various factors, potentially introducing bias from patient enrollment into the effectiveness evaluations. Future studies should implement strategies to minimize loss to follow-up to better assess treatment effectiveness and safety. Third, this study primarily enrolled treatment-naïve patients and did not include those with decompensated cirrhosis or long-term follow-ups after SVR12. Therefore, validation of these findings in a more diverse, larger cohort of Chinese patients and assessment of long-term impacts such as cirrhosis, liver transplantation, or HCC is warranted. Further in-depth investigation may help clarify the clinical benefits and accessibility of this regimen while addressing current limitations in study methodology and sample size.

The coblopasvir plus sofosbuvir regimen demonstrated good effectiveness and safety across genotypes and comorbidities in a real-world setting. It is therefore expected to guide future research and clinical practice.

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Conflict of interest

The authors have no conflict of interests related to this publication.

Author contributions

Conceptual design of the study (YHW, YZ), data collection (LMR, XCZ, XYZ, QQZ, QNZ, CLF, YBH), statistical analysis, and writing of the original draft (LMR, XCZ, XYZ). All authors reviewed and approved the final version and publication of the manuscript.

Ethical statement

The study was approved by the Medical Ethics Committee of The Third Affiliated Hospital of Wenzhou Medical University (Approval No.: YJ2025032; Date of issue: 5 March 2025) and conducted in accordance with the principles of the Declaration of Helsinki (as revised in 2024). Informed consent was obtained from all individual participants included in the study.

Data sharing statement

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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