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Efficacy and Safety of Glecaprevir/Pibrentasvir in Chronic Hepatitis C Patients: Real-World Data

Kronik Hepatit C Hastalarında Glekaprevir/Pibrentasvir'in Etkinliği ve Güvenliği: Gerçek Yaşam Verileri

Tayşi and Gezer. The Efficacy and Safety of Glecaprevir/Pibrentasvir

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Abstract
Introduction: Glecaprevir/pibrentasvir (G/P) is a pan-genotypic direct-acting antiviral therapy approved for use in adults with chronic hepatitis C virus (HCV) infection. This study aimed to assess the real-world efficacy and safety profile of G/P in individuals with chronic HCV.
Materials and Methods: The analysis included patients over 18 years with detectable HCV-RNA who began G/P treatment for chronic HCV between January 1, 2021, and March 1, 2024. The primary outcome measure was sustained virologic response (SVR), defined as undetectable HCV-RNA 12 weeks after therapy completion. Safety and tolerability of the regimen were also evaluated.
Results: G/P was administered to 191 patients, of whom 85.5% were male. Among them, 124 patients (64.9%) reported intravenous drug use. The most frequently identified genotype was GT 3 (57.1%). At 12 weeks post-treatment, 105 patients returned for follow-up, and all achieved SVR12. Adverse events occurred in 12 patients (6.3%). One patient discontinued treatment at week 4 due to pruritus and rash.
Conclusion: G/P demonstrates high effectiveness, good tolerability, and a favorable safety profile as a pan-genotypic therapeutic option for chronic HCV infection.
Keywords: HCV, chronic hepatitis C, glecaprevir/pibrentasvir, direct-acting antivirals, real-world efficacy

Öz
Giriş: Glekaprevir/pibrentasvir (G/P), kronik hepatit C virüsü (HCV) enfeksiyonu olan yetişkinlerin tedavisi için onaylanmış, pan-genotipik, doğrudan etkili bir antiviral rejimdir. Bu çalışmanın amacı, kronik HCV hastalarında G/P'in gerçek yaşam etkinliğini ve güvenliğini araştırmaktır.
Gereç ve Yöntem: 1 Ocak 2021 ile 1 Mart 2024 tarihleri arasında, kronik HCV enfeksiyonu için G/P tedavisi başlanan, tespit edilebilir HCV-RNA'sı olan, 18 yaş üstü hastalar analiz edildi. Birincil sonlanım noktası olan sürekli virolojik yanıt (SVR), tedavinin tamamlanmasından 12 hafta sonra tespit edilemeyen HCV-RNA olarak tanımlandı. Ayrıca G/P'nin güvenliği ve tolere edilebilirliği de değerlendirildi.
Bulgular: Toplam 191 hasta (%85,5 erkek) G/P ile tedavi edildi. Bunlardan 124'ü (%64,9) intravenöz uyuşturucu kullanıcısıydı. En yaygın genotip (GT) GT 3'tü (%57,1). Tedavinin tamamlanmasından on iki hafta sonra, 105 hasta takibe katıldı ve hepsi SVR12'ye ulaştı. Yan etki 12 hastada (%6,3) gözlendi. Bir hastada tedavi, 4. Haftada, kaşıntı ve döküntü nedeniyle kesildi.
Sonuç: G/P, kronik HCV enfeksiyonu olan hastalar için oldukça etkili, iyi tolere edilen ve güvenli bir pan-genotipik tedavi seçeneğidir.
Anahtar sözcükler: Hepatit C virüsü, tedavi, glecaprevir, pibrentasvir

Introduction

Hepatitis C virus (HCV) infection represents a major global public health concern. Among those infected, 75%-85% develop chronic infection, which can progress to severe conditions such as cirrhosis and hepatocellular carcinoma[1]. An estimated 50 million individuals globally are affected by chronic HCV infection, with approximately 1 million new cases reported each year[2]. In Türkiye, studies have shown that HCV prevalence ranges from 0.5% to 1%, with genotype 1b being the most prevalent[3-5].

The introduction of direct-acting antivirals (DAAs) in recent years has led to improved sustained virologic response (SVR) rates and reduced incidence of adverse events. Among these therapies is glecaprevir/pibrentasvir (G/P), which combines an NS3/4A protease inhibitor with an NS5A inhibitor. This regimen has a high barrier to resistance and is effective against all HCV genotypes. It is approved for use in patients without cirrhosis or with compensated cirrhosis. Previous research has shown that G/P treatment achieves SVR rates of 95%-100%, with most commonly reported adverse events being fatigue and headache[6-8].

The objective of this study was to evaluate the efficacy and safety of G/P in HCV-infected individuals using real-world data.

Materials and Methods

This retrospective study included patients over the age of 18 with chronic HCV infection and detectable HCV-RNA, regardless of prior HCV treatment status, who were seen at the Infectious Diseases and Clinical Microbiology outpatient clinic of Konya Chamber of Commerce (KTO) Karatay University between January 1, 2021, and March 1, 2024, and initiated on combination therapy with G/P. Patients were excluded if they were under 18 years of age, had hepatocellular carcinoma, had a history of liver transplantation, or were pregnant or breastfeeding. In Türkiye, G/P therapy is covered by the national health insurance for treatment-naive, non-cirrhotic patients regardless of HCV genotype, and liver biopsy is not required for reimbursement.

Baseline and end-of-treatment data were collected, including demographic characteristics, risk factors for HCV infection, history of previous HCV treatments, HCV genotype, and laboratory parameters such as alanine aminotransferase (ALT), aspartate aminotransferase (AST), alpha-fetoprotein (AFP), and platelet count (PLT). HCV-RNA levels were assessed at baseline, weeks 4 and 8 of therapy, and 12 weeks after completing treatment. Since no patients underwent liver biopsy and elastography was unavailable at the study site, liver fibrosis status was evaluated using the AST-to-platelet ratio index (APRI) and fibrosis-4 (Fib-4) scores. The Fib-4 score was calculated based on Sterling's formula[9]: Age (years) × AST

(IU/L)/PLT (10^9/L)x√ALT (IU/L). The APRI score was determined using Wai's formula[10]: (AST/upper limit of normal)/PLT (10^9/L)x100. Both scores were assessed at the initiation and completion of G/P therapy.
HCV-RNA levels were assessed using the AltoStar HCV RT-PCR kit, which has a detection range of 25 IU/ml to 1x10^7 IU/ml. An SVR at 12 weeks (SVR12) was defined as undetectable HCV-RNA at 12 weeks following the completion of G/P therapy.
The primary endpoint of the study was the SVR12 rate associated with the G/P regimen. Secondary endpoints included changes in liver fibrosis indicators (APRI, Fib-4) and selected biochemical markers (AST, ALT, AFP) in patients receiving G/P, VR rates at weeks 4 and 8 (defined as undetectable HCV-RNA level at 4 and 8 weeks after treatment initiation), the profile of drug-related adverse events, and the frequency of adverse events.
This study received approval from the KTO Karatay University Clinical Research Ethics Committee (approval number: 2024/012, dated: 06.06.2024) and was conducted in accordance with the Declaration of Helsinki.

Statistical Analysis

Categorical variables were reported as frequencies and percentages. Continuous variables were presented as mean ± standard deviation or as median (minimum-maximum). As the continuous variables did not follow a normal distribution based on the Kolmogorov-Smirnov test, non-parametric methods were applied. The Wilcoxon signed-rank test was used to compare continuous variables before and after treatment. Statistical analyses were conducted using IBM SPSS version 26.0 (IBM SPSS, Chicago, IL), and a p-value of <0.05 was considered statistically significant.

Results

A total of 191 patients were included in the study. Of these, 169 (85.5%) were male, with a median age of 30 years (range 18-83). Intravenous drug use (IVDU) was reported in 124 patients (64.9%). None of the patients had cirrhosis. HCV genotype analysis was performed in 112 patients (59%): GT 3 in 57.1%, GT 1b in 15.2%, GT 1a in 12.5%, GT 2 in 8.9%, and GT 4 in 6.4%. Among patients who reported IVDU, GT 3 was found in 66.2% and GT 1a in 19.1% (Table 1). The mean baseline HCV-RNA level was 2,475,512 IU/ml. Median ALT and AST levels were 55 U/L and 35 U/L, respectively. The median APRI and Fib-4 scores at baseline were 0.4 and 0.6, respectively. Five patients had a history of prior treatment for chronic HCV infection (two received sofosbuvir plus ribavirin, and three received interferon plus ribavirin). Among these, three had GT 3 and two had GT 1b.
All patients were prescribed an 8-week course of G/P therapy. Among those who completed follow-up at weeks 4 and 8, VR rates were 91.4% (32/35) and 100% (131/131), respectively. The three patients who did not achieve a VR at week 4 were all treatment-naive and infected with GT 3. Each of these patients subsequently achieved VR and SVR12 by week 8 post-treatment. At 12 weeks after treatment completion, 105 patients returned for follow-up, and all achieved SVR12 (per-protocol efficacy, 105/105 [100%]; intention-to-treat 105/191 [55%]) (Table 1). A statistically significant reduction was observed in ALT (p<0.001), AST (p<0.001), and APRI scores (p <0.001) at week 8 compared to baseline. No significant change was noted in AFP levels or Fib-4 scores (Table 2).
A total of 19 adverse events were reported in 12 patients (12/191, 6.3%): headache in 6 patients, fatigue in 4, pruritus in 3, rash in 3, and nausea in 3. Four patients experienced both headache and fatigue, while three patients had concurrent pruritus and rash. One patient with pruritus and rash discontinued G/P therapy at week 4 due to persistent symptoms despite antihistamine use. This patient achieved a VR at week 4 and SVR12 (Table 1).

Discussion

This real-world study demonstrated a 100% SVR rate among non-cirrhotic HCV patients treated with the G/P regimen. Real-world multicenter studies have similarly reported SVR rates with G/P ranging from 95% to 100%[5-8,11].
According to international guidelines, an 8-week G/P regimen is recommended for treatment-naive HCV patients without cirrhosis. However, baseline NS5A polymorphisms such as A30K and Y93H are known to confer high resistance to NS5A inhibitors, potentially reducing SVR12 rates in treatment-experienced patients with GT 3. For this reason, a 12-week G/P treatment course is advised for GT 3-infected patients with prior treatment experience and no cirrhosis[12-14]. In this study, all patients were non-cirrhotic and the majority were treatment-naive. All patients received an 8-week course of G/P therapy. Contrary to guideline recommendations, three treatment-experienced patients with GT 3 also received 8 weeks of therapy, and all achieved SVR12.
Shorter treatment durations with G/P may enhance access to therapy by lowering healthcare costs and improving patient adherence. A multinational study assessing the efficacy of a 4-week G/P regimen in individuals with HCV infection found that although 87% achieved HCV-RNA negativity at week 4, the SVR12 rate was only 78%, indicating reduced effectiveness compared to longer treatment durations[15]. In the present study, the virologic response rate at week 4 was 91.4%. However, since all patients were treated with an 8-week regimen, the efficacy of shorter treatment durations was not assessed.
In contrast to earlier studies identifying GT 1b as the most prevalent in Türkiye[3-5,16], over half of the patients in this study had HCV GT 3. This discrepancy in genotype distribution may be due to differences in the demographic characteristics of the study population compared to the general population in Türkiye. The high proportion of IVDU among the study participants supports this explanation. Although previous research suggests that the efficacy of G/P may be reduced in patients with GT 3[13,17], all patients with this genotype in our study achieved SVR12 following 8 weeks of treatment.
Earlier studies have shown that treatment of chronic HCV with DAAs is associated with improvements in noninvasive markers of liver fibrosis[18-20]. In our study, APRI scores significantly decreased after G/P therapy, while Fib-4 scores did not show a similar regression.
Overall, G/P was well tolerated in this study, with adverse event rates considerably lower than those reported in registration trials. Headache and fatigue were the most frequently reported adverse events. None of the adverse events were fatal. Only one patient discontinued treatment due to pruritus and rash. The observed safety and tolerability were consistent with those reported in registration studies[21].

Study Limitations

This study has several limitations due to its retrospective, real-world design. First, some clinical information may be incomplete or inaccurately documented. Additionally, adverse events might have been underreported, which could affect the interpretation of drug safety. Furthermore, since the study was conducted at a single center, the generalizability of the results is limited. Therefore, further research involving multiple centers from different regions of Türkiye is needed.

Conclusion

G/P is a highly effective, well-tolerated, and safe pan-genotypic treatment for patients with chronic HCV infection. Broadening access to this therapy could play an important role in efforts to eliminate HCV.

Ethics

Ethics Committee Approval: This study received approval from the KTO Karatay University Clinical Research Ethics Committee (approval number: 2024/012, dated: 06.06.2024) and was conducted in accordance with the Declaration of Helsinki.
Informed Consent:

Footnotes

Authorship Contributions

Surgical and Medical Practices: M.R.T., Y.G., Concept: M.R.T., Y.G., Design: M.R.T., Y.G., Data Collection or Processing: M.R.T., Y.G., Analysis or Interpretation: M.R.T., Y.G., Literature Search: M.R.T., Writing: M.R.T.
Conflict of Interest: No conflict of interest was declared by the authors.
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Table 1. Baseline characteristics of patients and treatment efficacy of G/P and G/P-related adverse events	
	n=191
Male n (%)	169 (88.5%)
Age	
Mean ± SD	33.9±14

Median (minimum-maximum)	30 (18-83)
IV drug user n (%)	124 (64.9%)
Treatment experience, n(%)	
HCV treatment-naïve	186 (97.4%)
HCV treatment-experienced	5 (2.6%)
HCV genotype, n(%)	
Genotype 1a	14 (12.5)
Genotype 1b	17(15.2)
Genotype 2	10 (8.9)
Genotype 3	64 (57.1)
Genotype 4	7 (6.3)
Unknown	79 (41.4%)
HCV-RNA (mean) (IU/ml)	2.475.512
G/P efficacy n(%)	
Virologic response at week 4*	31 (91.4%)
Virologic response at week 8**	131 (100%)
SVR12***	105 (100%)
AE's n (%)	
Patients with any AEs	12 (6.3)
AEs leading to G/P discontinuation****	1 (<1)[a]
AEs profile	
Headache	6 (3.1)
Fatigue	4 (2.1)
Itching	3 (1.6)
Rash	3 (1.6)
Nausea	3 (1.6)

*4th week evaluation available in 35 patients, ** 8th week evaluation available in 131 patients, ***SVR12 evaluation available in 105 patients, ****for itching and rash. G/P: Glecaprevir/pibrentasvir, SVR12: Sustained virologic response at 12 weeks, AE: Advers event, SD: Standard deviation, HCV: Hepatitis C virus

Table 2. Laboratory values and fibrosis scores of patients before and after G/P treatmen

	Pre-treatment Median (minimum-maximum)	Post-treatment Median (minimum-maximum)	**p-value**
AST (U/l)	35 (11-842)	17 (7-70)	<0.001
ALT (U/l)	55 (9-986)	14 (5-68)	<0.001
AFP (µ/l)	2.5 (0.9-14.9)	2.5 (0.9-16)	0.08
PLT (10^3/µl)	243 (36-690)	246 (53-431)	0.878
APRI score	0.4 (0.1-10.6)	0.2 (0.1-2)	<0.001
Fib-4 score	0.6 (0.1-11.2)	0.6 (0.3-7.8)	0.138

ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, AFP: Alpha-fetoprotein, G/P: Glecaprevir/pibrentasvir PLT: Platelet count, APRI: Aspartate aminotransferase-to-platelet ratio index, Fib-4: Fibrosis-4