Research Article

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Real-World Data on the Use of Glecaprevir/Pibrentasvir in the Treatment of Hepatitis C: Is Shorter Treatment Possible?

Hepatit C Tedavisinde Glekaprevir/Pibrentasvir'in Gerçek Dünya Verileri: Daha Kısa Tedavi Mümkün mü?

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ABSTRACT

Objectives: This study aimed to present real-world data on the efficacy of glecaprevir/pibrentasvir (G/P) in chronic hepatitis C (CHC) patients treated at our center.

Materials and Methods: Non-cirrhotic, treatment-naive, and treatment-experienced (TN/TE) CHC patients with CHC who started G/P treatment in 2022 were included in this retrospective, cross-sectional, single-center, national study. Sustained virological response (SVR) was defined as undetectable hepatitis C virus-ribonucleic acid (HCV-RNA) for at least 12 weeks following the discontinuation of antiviral therapy.

Results: Sixty patients with non-cirrhotic TN/TE CHC who started G/P were included in the study. All patients received G/P treatment for 8 weeks. The median age of the patients was 45 years (interquartile range 22-3) and 44 (73.3%) were males. The most frequently identified risk factor for CHC was substance use (n=7, 11.7%), whereas the most common comorbidities were cardiovascular disease, hypertension (n=8,13.3%), and diabetes mellitus (n=7, 11.7%). HCV genotype was evaluated in all patients. Genotype distribution: Genotype 1b was detected in 53 patients (88.3%) and genotype 1 was detected in 7 patients (11.7%). The median pretreatment HCV-RNA level of the patients was 137,000 IU/mL. HCV-RNA was evaluated in all patients at the 4th and 8th weeks of treatment and at the 12th week after treatment. All patients were HCV-RNA-negative in the 1st month of treatment.

ÖZ

Amaç: Bu çalışmanın amacı, merkezimizde tedavi edilen kronik hepatit C (KHC) hastalarında glekaprevir/pibrentasvir (G/P) etkinliğine ilişkin gerçek dünya verilerini sunmaktır.

Gereç ve Yöntemler: Bu retrospektif, kesitsel, tek merkezli, ulusal çalışmaya 2022 yılında G/P tedavisine başlayan sirotik olmayan, tedavi naif ve tedavi deneyimli (TN/TE) koroner kalp hastalığı (KKH) hastaları dahil edilmiştir. Kalıcı virolojik yanıt (KVY), antiviral tedavinin kesilmesini takiben en az 12 hafta boyunca tespit edilemeyen hepatit C virüsü-ribonükleik asit (HCV-RNA) olarak tanımlanmıştır.

Bulgular: Çalışmaya G/P başlanan sirotik olmayan TN/TE KHC'li 60 hasta dahil edilmiştir. Tüm hastalar 8 hafta boyunca G/P tedavisi almıştır. Hastaların ortanca yaşı 45 (çeyrekler arası aralık 22-3) ve 44'ü (%73,3) erkekti. KKH için en sık tanımlanan risk faktörü madde kullanımı (n=7, %11,7) iken, en yaygın komorbiditeler kardiyovasküler hastalık, hipertansiyon (n=8, %13,3) ve diabetes mellitus (n=7, %11,7) idi. Tüm hastalarda HCV genotipi değerlendirilmiştir. Genotip dağılımı: 53 hastada (%88,3) genotip 1b ve 7 hastada (%11,7) genotip 1 saptandı. Hastaların tedavi öncesi medyan HCV-RNA düzeyi 137.000 IU/mL idi. HCV-RNA tüm hastalarda tedavinin 4. ve 8. haftalarında ve tedaviden sonraki 12. haftada değerlendirilmiştir. Tüm hastalar tedavinin 1. ayında HCV-RNA negatifti. Ayrıca, tedavi sonunda ve 12 haftalık takipte tüm hastalarda HCV-RNA negatifliği devam etmiştir. Tedavi sırasında

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Additionally, HCV-RNA negativity continued in all patients at the end of treatment and at 12 week follow-up. No mild, moderate, or serious adverse events were observed during or after treatment. All patients were successfully treated.

Conclusion: All patients extremely well tolerated the drug. The SVR response was found to be 100%. In addition, the fact that the viral load of all patients in our study was negative in the 4th week of treatment suggested the possibility of shorter-term treatment. More studies on this subject.

Keywords: Hepatitis C, real-life data, treatment responses

veya sonrasında hafif, orta veya ciddi advers olay gözlenmemiştir. Tüm hastalar başarıyla tedavi edilmiştir.

Sonuç: Tüm hastalar ilacı son derece iyi tolere etmiştir. KVY yanıtı %100 olarak bulunmuştur. Ayrıca, çalışmamızdaki tüm hastaların viral yükünün tedavinin 4. haftasında negatif olması, daha kısa süreli tedavi olasılığını düşündürmüştür. Bu konuda daha fazla çalışma yapılmalıdır.

Anahtar Kelimeler: Hepatit C, gerçek yaşam verileri, tedavi yanıtları

Introduction

Globally, an estimated 58 million people have chronic hepatitis C virus (CHC) infections, and approximately 1.5 million new infections occur each year. The World Health Organization (WHO) estimates that approximately 290,000 people died from hepatitis C in 2019, mostly from cirrhosis and hepatocellular carcinoma (1). The elimination of viral hepatitis has been accepted as a public health goal by the World Health Assembly for 2030 (2). After the first direct-acting antivirals (DAAs) were approved by the US Food and Drug Administration in 2011, more than 10 pharmaceuticals (including those effective against all genotypes) are currently available. The WHO recommends pan-genotypic DAA agents for all adult patients infected with hepatitis C virus (HCV) (1).

Glecaprevir/pibrentasvir (G/P) is a fixed-dose combination of the HCV NS3/4A protease inhibitor G and the HCV NS5A inhibitor P. They are DAA agents with pangenotypic activity and a high resistance barrier. The recommended G/P dose is 300/120 mg (three tablets of 100 mg/40 mg) once a day with food (3). G/P has been shown to be highly effective and tolerable in various studies (4,5,6). Guidelines now recommend pan genotypic effective regimens for simplified HCV treatment in patients with cirrhosis and compensated cirrhosis (CC) (7,8). G/P was shown to have a positive safety profile in a phase 3 study conducted in treatment-experienced (TE) or treatment-naive (TN) patients with chronic HCV genotypes 1, 2, 4, 5, or 6 infection and CC (9).

Nowadays, we are talking about cure because of the new generation DAAs, which are very effective against CHC. In this study, we aimed to present our real-life data on G/P in non-cirrhotic, TE/TN CHC patients and to examine whether shorter-term treatment is possible.

Materials and Methods

This retrospective, cross-sectional, single-center, and national study included 60 patients who received G/P treatment at our hospital in 2022. Patients' data [sociodemographic characteristics (age, gender, mode of transmission), laboratory (viral load, HCV genotype-subtype, aspartate aminotransferase (AST), alanine aminotransferase (ALT), gamma-glutamyl transferase (GGT), alkaline phosphatase (ALP), platelet, international normalized ratio, alpha fetoprotein (AFP), total bilirubin) and radiological findings before and during treatment, treatment-related side effects and comorbidities] were retrospectively collected.

Non-cirrhotic, TN/TE patients aged >18 years, infected with genotypes 1 and 1b of HCV for more than six months were included in the study. Considering national and international guidelines, all non-cirrhotic patients with TN/TE were treated with three tablets of G/P per day with food for 8 weeks (3,10). Patients were evaluated in terms of clinical, virological, and biochemical improvement and adverse events in the fourth, eighth, and twelfth weeks of treatment. Follow-up of patients whose treatment was completed was continued every 3 months to determine sustained virological response (SVR).

SVR was defined as undetectable HCV-ribonucleic acid (RNA) for at least 12 weeks after the end of antiviral therapy. The primary endpoint was SVR achievement. The secondary endpoints were virological responses at week four and at the end of treatment (eighth or twelfth week).

Statistical Analysis

IBM SPSS 21.0 for Windows statistical package was used for the statistical evaluation of the research data. Quantitative variables are presented as mean ± standard deviation, and categorical variables are presented as number and percentage (%). The Kolmogorov-Smirnov test was used to determine whether the data conformed to the normal distribution. Not normally distributed; Friedman test was used to compare the baseline, 4th, 8th, and 12th week data. The hypotheses were two-sided; a statistically significant result was accepted if $p \leq 0.05$.

Ethical Permission

This study was approved by the Dicle University Faculty of Medicine Non-interventional Clinical Research Ethics Committee (approval number: 242, date: 13.09.23).

Results

This study included 60 patients with non-cirrhotic, TN/TE, CHC who were treated with G/P for 8 weeks at our hospital in 2022. The baseline characteristics and pretreatment laboratory results of all patients are presented in Table 1. The median age of the patients was 45 years (interquartile range 22-73) and 44 (73.3%) were males. The most frequently identified risk factor for CHC in the study population was substance use (n=7, 11.7%), whereas the most common comorbidities were cardiovascular disease, hypertension (n=8, 13.3%), and diabetes mellitus (n=7, 11.7%). HCV genotype was evaluated in all patients. Genotype distribution: Genotype 1b was detected in 53 patients (88.3%) and genotype 1 was detected in 7 patients (11.7%).

Laboratory data before treatment and changes in parameters during the first month of treatment and at the end of treatment

are presented in Table 2. The results of patients whose laboratory parameters were recorded during all three periods were analyzed. No statistically significant differences were found in the parameters ALT, AST, GGT, AFP, albumin, ALP, total bilirubin, and platelet and prothrombin time, which are evaluated as biomarkers for liver health at the beginning, 4th week, and end of treatment.

The median pre-treatment HCV-RNA level of all patients was 137,000 IU/mL. HCV-RNA was evaluated in all patients at the 4th and 8th weeks of treatment and at the 12th week after treatment. In the first month of treatment, all patients were HCV-RNA-negative. In addition, HCV-RNA negativity continued in all patients at the end

Table 1. Baseline characteristics of patients before treatment

	n=60
Age > year, median (IQR)	45 (22-73)
Sex, n (%)	
Male Female	44 (73.3) 16 (26.7)
Risk factors, n (%)	
Substance abuse Blood products Surgical contamination Unknown	7 (11.7) 5 (8.3) 6 (10) 41 (68.3)
Comorbidities, n (%)	
Diabetes mellitus Hypertension Heart disease Substance abuse Alcohol	7 (11.7) 8 (13.3) 8 (13.3) 3 (5) 3 (5)
Genotype, n (%)	
Gp1 Gp1b	7 (11.7) 53 (88.3)
Pretreatment laboratory data	
HCV-RNA level, IU/mL; median (IQR) Platelets, x10^3/µL Prothrombin time Creatinine, mg/dL Albumin, g/dL ALT, U/L AST, U/L GGT, U/L ALP, U/L Total bilirubin level, mg/dL AFP, IU/mL	137.000 (3780-810.900) 212.000 (110000-290000) 14.4 (11.1-16.1) 1.1 (0.5-1.6) 3.2 (2.9-4.4) 36 (25-56) 44 (21-54) 32 (25-50) 108 (72-131) 1.1 (0.7-1.6) 3.1 (1.2-3.4)
Treatment duration	
8 weeks, n (%)	60 (100)
Treatment experience n (%)	
No Yes PEG + RBV Ombitasvir/paritaprevir/ritonavir + dasabuvir Telaprevir + PEG + RBV	27 (45) 33 (55) 22 (36.7) 10 (16.7) 1 (1.7)

IQR: Interquartile range, HCV: Hepatitis C virus, RNA: Ribonucleic acid, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, GGT: Gamma glutamyl transferase, ALP: Alkaline phosphatase, AFP: Alpha-fetoprotein, PEG: Pegile interferon, RBV: Ribavirin

Table 2. Pre-treatment, 1st-2nd month of treatment, and post-treatment laboratory data

	Pretreatment values		**4 week**		**8 week**		**12 week**		
	x ± SD	**Median (IQR) (min.-max.)**	**X + SD**	**Median (IQR) (min.-max.)**	**x + SD**	**Median (IQR) (min.-max.)**	**x + SD**	**Median (IQR) (min.-max.)**	**p***
HCV-RNA	962.415±1724604	137000 (3780-8109000)	-	-	-	-	-	-	**0.000**
Platelets	204.4±42.2	212 (110-290)	202.15±52.053	189.5 (110-345)	204.38±50.817	212 (110-389)	185.92±41.885	178 (110-290)	0.456
Albumin	3.23±0.31	3.2 (2.9-4.4)	3.19±0.28	3.2 (2.9-4.8)	3.182±0.2318	3.2 (2.9-3.9)	3.235±0.2462	3.2 (2.9-4.3)	0.976
ALT	38.93± 10.519	36.00 (25-56)	40.35± 10.281	36 (25-55)	40.50±9.871	40 (26-55)	40.67±10.424	36 (26-55)	0.847
AST	41.13±7.71	44.00 (21-54)	41.7±7.663	44 (21-54)	41.93±7.353	44 (25-54)	42.45±7.550	44 (25-54)	0.710
GGT	34.77±11.194	32 (25-80)	32.32±4.284	31 (28-49)	31.43±3.207	31 (28-39)	31.80±3.602	31 (28-44)	0.116
ALP	106.92±17.712	108 (72-131)	101.45± 17.447	104 (72-129)	101.00±19.075	108 (28-129)	103.97±18.119	109 (72-129)	0.023
TB	1.137±0.2718	1.100 (0.7-1.6)	1.138±0.2457	1.100 (0.7-1.6)	1.130±0.2606	1.2 (0.7-1.6)	1.198±0.2514	1.2 (0.7-1.6)	0.167
AFP	2.943±0.5628	3.1 (1.2-3.4)	2.903±0.6561	3.1 (1.2-3.7)	2.922±0.6181	3 (1.2-3.9)	2.902±0.6074	3 (1.2-4)	0.801
PT	14.1±1.14	14.4 (11.1-16.1)	14.0±0.9441	14.1 (12.2-16.1)	14.0±0.9898	14.1 (12.2-15.2)	13.943±0.9194	13.8 (12.2-15.2)	0.507
Cre	1.052±0.2587	1.100 (0.5-1.6)	1.007±0.2510	1.1 (0.5-1.6)	1.0±0.2123	1.100 (0.5-1.3)	1.040±0.1825	1.1 (0.5-1.3)	0.730

*Friedman test. HCV: Hepatitis C virus, RNA: Ribonucleic acid, ALT: Alanine aminotransferase, AST: Aspartate aminotransferase, GGT: Gama glutamyl transferase, ALP: Alkaline phosphatase, TB: Total bilirubin, AFP: Alpha-fetoprotein, PT: Prothrombin time, Cre: Creatinine, SD: Standard deviation, IQR: Interquartile range, max.: Maximum, min.: Minimum

of treatment and at the 12 week follow-up. No mild, moderate, or serious adverse events were observed during or after treatment. All patients were successfully treated.

Discussion

In this study, the results of real-world data on G/P in CHC patients are presented. The SVR rate of G/P in TE/TN CHC patients was 100%, supporting the notion that G/P treatment is effective and tolerable. The high SVR rate with G/P in our study is compatible with many studies that reported the use of G/P for both 8 and 12 weeks of treatment (11,12,13,14,15). Another efficacy and safety study was performed in 102 patients in Korea. G/P therapy proved to be highly effective, with 97.1% of all patients achieving SVR 12, regardless of the presence of CC or the patient's previous CHC treatment experience. Although not statistically significant in this study, there was a difference in the proportion of patients achieving SVR 12 between those receiving 8 weeks of treatment and those receiving 12 or 16 weeks of treatment (98.8% vs. 90.5%, p=0.107). The 12 and 16 week treatment periods consisted of CC and TE patients. The results also showed that liver fibrosis improved after G/P treatment. Pruritus was the most common adverse event (10.8%), followed by fatigue (2.9%), headache (2.0%), and gastrointestinal disturbances (3.9%) were also reported (16). In our study, the fact that viral load was not detected in all patients in the 4th week of treatment indicated that the effectiveness of treatment was high.

In SURVEYOR-I (for genotypes 1, 4, 5 and 6) and SURVEYOR-II (for genotypes 2 and 3), final data from study arms showed an eight-week treatment course of G/P was evaluated in both CC patients and patients with non-cirrhotic genotype 2-6 infection, achieving an overall SVR12 rate of 97% rates were obtained (17). When these data are evaluated although there are no data on reducing the treatment duration, more studies are necessary due to effective responses. In the VOYAGE 1 study, SVR12 was achieved in 352 out of 362 patients with non-cirrhosis who received G/P (97.2%). In VOYAGE-2, 159 out of 160 compensated patients with cirrhosis achieved SVR12 (99%) (18). In EXPEDITION-1, a single-arm, open-label, multicenter phase 3 study, the efficacy and safety of G/P was demonstrated with a 12 week treatment period in TN/TE-CC patients (19). Subsequently, the labeled duration of G/P therapy for TN patients with CC was changed from 12 weeks to 8 weeks for genotypes 1, 2, 4, 5, and 6 in July 2019 and for genotype 3 in March 2020. A highly SVR was achieved with the results of this EXPEDITION-8 study, which led to the addition of 8 weeks of G/P, which is a shorter treatment for CHC in the AASLD and EASL guidelines (3,14). Real-world data demonstrated comparable efficacy of G/P when administered for 8 or 12 weeks in patients with TN/CC CHC (intention-to-treat: 97.4% and 98.1%, respectively) (9,12). Analysis of relevant populations conducted in the same study revealed SVR12 rates of ≥95% regardless of comorbidities. It has been reported in many studies that accompanying diseases and risk factors do not affect SVR (20,21). In our study, comorbidities and substance use, which are the most common risk factors, did not affect the sustained virologic response rates. In addition, the HCV-RNA negativity obtained in all patients at week 4 in our study suggests the possibility of shorter-term treatment with G/P. Today, the leading cause of treatment failure in CHC treatment is medication non-compliance, especially in key populations. Therapeutic strategies with shorter durations are currently being evaluated and may be particularly useful in key populations and in certain settings. Predicting who may respond to short-term treatment with DAAs agents will have important implications for models of care in "hard-to-reach" populations, such as incarcerated patients, people hospitalized with serious injection-related infections, those with psychiatric illnesses, and those with drug-related comorbidities. In the TARGET3D study, which evaluated the effectiveness of 4 weeks of G/P treatment in people with recent (<12 months) HCV infection, the effectiveness was associated with baseline HCV-RNA. In this study, all participants with a baseline HCV-RNA <6.5 log 10 IU/mL achieved SVR (15/15, 100%). Conversely, most participants with baseline HCV-RNA levels >7 log 10 IU/mL (3/5, 60%) experienced virologic failure. The effectiveness of 4 week G/P treatment was lower than that observed with longer treatment durations (≥6 weeks) (22). On the contrary, G/P was found to be highly effective with a 6 week treatment period among people with acute and recent HCV infection (<12 weeks), which is called the hard-to-reach population (77% human immunodeficiency virus positive, 47% substance abusers, and 13% HCV reinfection), in a single-arm, multicenter, international pilot study (22).

Conclusion

Short-acting, pangenotypic DAAs, such as G and P, are increasingly important treatments that can support countries in achieving the WHO goal of eliminating hepatitis C virus (HCV). Our study shows, consistent with real-world evidence, that G/P is a well-tolerated and highly effective pangenotypic treatment for a broad range of HCV-infected patients. Shortening the treatment duration may help address the gaps in care in populations that are difficult to reach and follow.

Ethics

Ethics Committee Approval: This study was approved by the Dicle University Faculty of Medicine Non-interventional Clinical Research Ethics Committee (approval number: 242, date: 13.09.23).

Informed Consent: Retrospective study.

Authorship Contributions

Surgical and Medical Practices: A.Y.T., Ç.M., M.Ç., Concept: Ç.M., Design: Ç.M., Data Collection or Processing: M.Ç., Analysis or Interpretation: A.Y.T., Literature Search: Ç.M., M.Ç., Writing: A.Y.T., Ç.M., M.Ç.

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