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Research Article

ZOOLOGY

Biochemical study on the response to HCV therapy (Velpatasvir containing regimen), (vosevi) among adult patients' non-responders to treatment in Fayoum, Egypt

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KEY WORDS

DAAs, HCV, SVR, Velpatasvir, Vosevi

ABSTRACT

Oral medications for the treatment of hepatitis C virus (HCV) infection, direct-acting antiviral agents (DAAs) are recommended. Worldwide, DAAs-based regimens have achieved excellent cure rates with a respectable profile of safety and a higher sustained virological response (SVR) rate than earlier interferon-containing therapy combinations. SVR is not achieved in about 5% of HCV patients on DAAs medications. Sofosbuvir, velpatasvir, and voxilaprevir (SOF/VEL/VOX) is the recommended retreatment regimen after prior first line DAA failure. Therefore, the purpose of this study was to assess the effectiveness, safety and biochemical changes of using Velpatasvir containing regimen (vosevi) for 12 weeks in the studied population.

A prospective cohort study included 102 patients who had failed treatment with combination therapy (sofosbuvir and daclatasvir). Patients were recruited from the liver center at El-Fayoum health insurance. They were subjected to the DAA regimen (SOF/VEL/VOX). Laboratory tests were evaluated at baseline, 4 weeks, 8 weeks, end of treatment, and 12 weeks after treatment.

Our study showed that, after 12 weeks of treatment, 99 patients (97.1%) had a complete virologic response while 3 (2.9%) patients did not reach SVR12. In addition, mild side effects were detected in only 23.5% while the rest showed no adverse effects. Liver function tests during treatment and at SVR12 showed a considerable improvement.

Vosevi is an effective treatment for HCV patients who need to be treated again in Egypt with mild side effects.

Introduction

Approximately 58 million people worldwide are still affected by hepatitis C, and its effects continue to be severe. 1.5 million new infections per year average makes a considerable contribution to mortality and morbidity from liver disease **(WHO, 2022).** HCV elimination became a national health priority due to Egypt having the highest global prevalence of HCV infection, which is linked to significant disease and economic burden **(Blach *et al*., 2017).** HCV infection has been successfully under control by the Egyptian government with a high probability that the disease would be cured by 2030. In order to accomplish this, efforts should focus on the still-deficient degree of behavioral development as well as testing and treatment **(Metwally *et al*., 2021).**

The long-term implications of HCV infection can range greatly, from having no effects to developing cirrhosis, advanced fibrosis, decompensated cirrhosis, and hepatocellular carcinoma (HCC) **(Axley *et al*., 2017).** Rates of sustained virological response (SVR) to antiviral medication have grown considerably as a result of improved direct-acting antivirals (DAA), which have success rates above 95% in all patient categories for the treatment of HCV **("EASL Recommendations on Treatment of Hepatitis c 2016," 2017).** Even with the best efficacy and safety, some patients show resistance to DAAs still do not attain an SVR and require alternate therapeutic approaches. This issue may be resolved by sending patients back to treatment facilities and selecting the right re-treatment plan in accordance with the available protocol of therapy **(El Kassas *et al*., 2018).**

For retreatment adult patients with HCV genotypes 1:6 who do not have cirrhosis or compensated cirrhosis, including those taking the non-structural 5A inhibitor, only a pan-genotypic DAAs combination Sofosbuvir (SOF)/Velpatasvir (VEL), and the second-generation HCV protease inhibitor, Voxilaprevir (VOX), has been approved **(Da *et al*., 2020).**

SOF/VEL/VOX (Vosevi) is containing a fixed dose of a combination of 400 mg sofosbuvir, an NS5B polymerase inhibitor, 100 mg velpatasvir, an NS5A inhibitor, and 100 mg voxilaprevir, an NS3/4A protease inhibitor in a single tablet **(Highlights of Prescribing Information, 2017).**

Success SVR at week 12 and treatment failure (any HCV RNA that is still present) at the conclusion of the 12-week

treatment period will be the categories used to classify treatment outcomes **(Cheung *et al*., 2016).**

The aim of this study was to assess the effectiveness, safety and biochemical changes of using Velpatasvir containing regimen (vosevi) for 12 weeks in HCV-RNA-positive adult patients after treatment by (Sofosbuvir and daclatasvir) combination regimen with or without Ribavirin.

Patients and methods

In this prospective cohort study, 102 chronic HCV (HCV-RNA positive) adult patients who had not responded to sofosbuvir and daclatasvir combination therapy with or without ribavirin were included. Patients were recruited from the liver center at El- health insurance from September 2020 to December 2022 and were eligible for non-responders' treatment under the guidelines set by the National Committee for Control of Viral Hepatitis (NCCVH), which was founded by the Egyptian Ministry of Health and Populations in September 2019.

The requirements for including patients were: patient with HCV RNA positive, adult patients (both genders) (above 18 years old). The requirements for excluding patients were: infection with HBV, Platelet < 50000/mm3, HCC and extra-hepatic malignancy, Child's hepatitis C score > 8, being pregnant or inability to use effective contraception.

The same fixed-dose combined tablet was given to each patient (400 mg of sofosbuvir, 100 mg of velpatasvir, and 100 mg of voxilaprevir). For 12 weeks, one tablet was given orally once a day with food. The study has ethical approval from University Supreme Committee for Scientific Research Ethics (FU-SCSRE). All of the participants in the current study signed an approved consent.

For all patients, the following was carried out:

- **Clinical study:** full medical history and complete clinical assessment, with a focus on previous HCV treatment duration and the type as well as associated comorbidities and drugs.

- **Laboratory investigations:** HCV RNA by PCR Quantitative, Complete blood count, serum albumin (Alb), alanine aminotransferase (ALT), aspartate aminotransferase (AST), T.bilirubin, Prothrombin time and concentration, Serum creatinine, Alpha Feto protein, Fasting blood glucose, HBA1c: If the patient has diabetes, HBs Antigen .

- **Imaging**: Abdominal ultrasound to examine the liver and detect HCC (any detected HCC were excluded)**.**

- Patients assessment: Liver function tests were used to monitor patients throughout therapy. ALT, AST, T.bilirubin and CBC, S. creatinine at baseline, 4 weeks, 8 weeks, end of treatment, and 12 weeks after treatment any adverse effects that patients observed or reported were noted.

Post-treatment follow-up of patients

The laboratory tests were conducted at baseline and 12- week after completing therapy **is** HCV RNA by PCR Quantitative, CBC**,** ALT, AST, T. bilirubin**,** S.creatinine**,** Albumin**,** AFP**,** INR.

People who achieved SVR were retested for HCV RNA at 24 weeks post-treatment. The infection was defined as being completely cured if HCV RNA remained undetectable .

Primary outcome: Undetectable (HCV-RNA) level at 12 weeks (SVR 12).

Secondary outcome: Biochemical changes in the body functions (CBC, ALT, AST, T. bilirubin, Serum creatinine) and the side effects during the treatment period.

Ethical aspects

The study has ethical approval from University Supreme Committee for Scientific Research Ethics (FU-SCSRE), Scientific Research Ethics Committee at the Egyptian Ministry of Health and Populations (MOHP) and then by General Administration of Clinical Research in the General Authority for Health Insurance (HIO). All of the participants in the current study signed an approved consent.

Statistical analysis

Data were expressed in Number (No), percentage (%), mean (x), and standard deviation (SD), median and interquartile range (IQR).

Repeated measures ANOVA (with the Bonferroni correction) with the Mauchly test as a sphericity test were used for comparison among three or more consecutive measures in the same group of quantitative variables.

Statistical Package for Social Science version 28 was used for performing the statistical analysis (SPSS Inc. Released 2022. IBM SPSS statistics for windows, version 23.0, Armnok, NY: IBM Corp.).

For interpretation of results, Significance level (P) value was expressed as follows:

$P < 0.05$ = significant, $P > 0.05$ = non-significant.

Results

102 patients who failed to achieve SVR following a full course of SOF + DAC + RBV were included in this study.

According to protocol, SOF + VEL + VOX were used to treat all patients for 12 weeks. The mean age of the included patients was 55.67 ± 10.43 years. Patients were predominantly males (89 patients, 87.3%). Baseline demographic and clinical characteristics are shown in **(Table 1).**

Table (1): Baseline demographic and clinical characteristics (n =103)

Variables	**(%) n**
Age, Mean ± SD	**55.67 ± 10.43 years**
Sex	
Male	**89 (87.3)**
Female	**13 (12.7)**
Hypertension	
No	**92 (90.2)**
Yes	**10 (9.8)**
Diabetes	
No	**81 (79.4)**
Yes	**21 (20.6)**
Previous treatment	
Sof + DAC	**72 (70.6)**
SOF + DAC + RIB	**30 (29.4)**
HBs-Ag	
Positive	**0 (0.0)**
Negative	**102 (100)**
FBS, Median (IQR)	**132 (97)**
HBA1c, Median (IQR) (n=21)	**7.30 (1.47)**

Hemoglobin levels before treatment were significantly higher at week 4 compared to week 8 and week 12 (P<0.001), as well as all other weeks after that. The white blood cells median is gradually increases till week 8 (6.900), cells drop in week 12 (6.700) (P<0.001). There was a significant increase in the follow up weeks of platelet where the mean of platelets at week 24 is significantly higher than baseline (p<0.001).

The median of serum level of total bilirubin, ALT and AST were significant decreased gradually over the different time points till it reaches (0.5, 26.5, 23.0, respectively) at week 24 (p<0.001). Almost a steady state of creatinine was detected over different time points, however it increases at week 24 (1.00)

compared to baseline (0.93) (p<0.001) **(Table 2).**

The median of albumin and INR do not significantly differ at week 24 and at baseline (P=0.038, <0.004, respectively). The median of AFP at week 24 is significantly higher than the median of AFP at baseline (P<0.001) **(Table 3).**

The safety of antiviral treatment: (76.5%) of the cases showed no side effects for (VOSEVI) while the rest 24 patients (23.5%) showed mild side effects. Headache is the most predominant side effect detected in our patients followed by fatigue, diarrhea, nausea, asthenia, insomnia **(Table 4).**

Evaluating the efficacy of antiviral regimen at 12 weeks after completing therapy reveals that 99 patients (97.1%) achieved sustained virology response SVR12 **(Table 5).**

Assessment of the effectiveness of antiviral treatment Following up of the responders for another 12 weeks shows 100% sustained virological response at week 24 **(Table 6).**

Table (2): Laboratory result for patient n =102 from baseline to week 24

Variable*	Baseline	Week 4	Week 8	Week 12	Week 24	P value
HB	13.83±1.45	13.53±1.32	13.46±1.40	13.37±1.40	13.35±1.15	<.001
WBCs	5.950(2.5)	6.400(2.6)	6.900(2.9)	6.700(2.8)	6.400(2.4)	<0.001
PLTs	172.95±55.71	183.77±55.92	185.972±63.11	186.98±57.60	195.90±52.23	0.002
ALT	47.50(38)	38.00(15)	37.00(14)	35.00(12)	26.50(11)	<0.001
AST	38.00(30)	31.00(9)	29.00(9)	28.00(9)	23.00(8)	<0.001
T. Bil	0.79(0.37)	0.70(0.30)	0.60(0.30)	0.60(0.20)	0.50(0.20)	<0.001
creatinine	0.93 (0.25)	0.98(0.30)	0.98(0.22)	1.00(0.20)	1.00(0.20)	<0.001

Table (3): Laboratory result for patient N=102 between baseline and week 24

Variable	Baseline	Week24	P.value
Albumin	4.20(0.50)	4.10 (0.3)	0.038
AFP	5.55 (8.13)	5.75 (6.7)	<.001
INR	1.09 (0.15)	1.09 (0.12)	0.004

Table (4): Side effects in the studied patients (n=102)

Side effects	N	(%)
No side effects	78	(76.5)
With side effects	24	(23.5)
Fatigue	6	(5.9)
Diarrhea	4	(3.9)
Nausea	2	(2)
Asthenia	2	(2)
Insomnia	1	(0.9)

Table (5): Treatment outcome (12 weeks after completing therapy)

Total number of patient n=102	N	%
Achieved SVR12	99/102	97.1%
Didn't achieve SVR12	3/102	2.9%

Table (6): Treatment outcome (Follow up of the responders for another 12 weeks)

Total number of patients n=99	N	%
Achieved SVR24	**99/99**	**100%**

Discussion

This study evaluated the effectiveness, safety, and biochemical changes of using Velpatasvir containing regimen (vosevi) for 12 weeks in 102 chronic hepatitis C adult patients who had tested positive for the HCV RNA after receiving treatment by (Sofosbuvir and daclatasvir) combination regimen with or without Ribavirin in Egypt.

In this study, assessing the effectiveness of antiviral treatment revealed that 99/102 (97.1%) patients achieved sustained virology response while only 3 out of 102 patients (2.9%) were non-responders to treatment and didn't achieve sustained virological response after 12 weeks of treatment. Follow up of the responders for another 12 weeks all those patients revealed targeted sustained virology response.

Similar to **Sarrazin *et al.*, 2018** phase 3 study showed that treatment with SOF + VEL + VOX for 12 weeks in hepatitis C virus non responders to prior treatment with NS5A inhibitors experienced patients and NS5A non experienced patients resulted in cure rate 97% were achieved sustained virological response.

In the same line, large Canadian cohort study of 191 patients **Janjua *et al.*, 2020** evaluated the efficacy of SOF/VEL/VOX in treating treatment-experienced patients with genotype 1 (GT1) to genotype 6 (GT6) HCV infection. Overall, the SVR rate was 95.3% (182/191)**.**

In the current study, the safety of antiviral treatment showed that 76.5% of the cases showed no side effects while the rest 24 patients (23.5%) complained about mild side effects. No deaths or serious adverse events reported. Headache is the most predominant side effect detected in our patients with 9 patients (8.8%), followed by fatigue in 6 patients (5.9%), diarrhea in 4 patients (3.9%), nausea in 2 patients (2%), asthenia in 2 patients (2%), and insomnia in 1 patient (0.9%).

Similarly, **Bourlière *et al.*, 2017** noticed that the headache, fatigue, diarrhea, and nausea were the most frequent side effects in their two phase 3 trials with patients who had previously taken a regimen including DAA**.**

In this study, the median of serum level of total bilirubin, ALT and AST were significant decreased gradually over the different time points till it reaches (0.5, 26.5, 23.0, respectively) at week 24 ($p<0.001$). There was a significant increase in the follow up weeks of platelet where the mean of platelets at week 24 is significantly higher than baseline ($p<0.001$).

Among 45 patients who received SOF/VEL/VOX during 12-week **Shousha *et al.*, 2022** reported in their prospective cohort study three regimens for re-treatment failure of Sofosbuvir-based therapy for chronic hepatitis-C genotype-4 that levels of ALT, AST and platelet count significantly improved gradually during and after treatment. This agrees with our study. While there is no significant difference between the mean of T. bilirubin at baseline and over time, disagree with our study.

In current study there is no significant difference between the median of albumin and INR at week 24 and at baseline ($P=0.038$, <0.004, respectively). The median of AFP at week 24 is significantly higher than the median of AFP at baseline ($P<0.001$)

Elhammady *et al.*, 2020 were included in their study no statistical significance regarding serum albumin, bilirubin, INR and platelets count were detected. This disagrees with our study we detected a statistical significance regarding serum bilirubin and platelets count with no significant difference regarding albumin and INR.

Furthermore, **Shousha *et al.*, 2022** reported in their study among 45 patients who received SOF/VEL/VOX during 12-weeks that SVR12 was achieved in 97.8%. Prolonged INR were not detected among patients similar with our study.

Conclusion

In conclusion, Velpatasvir combination regimen Vosevi (Sofosbuvir/ Velpatasvir/ Voxilaprevir) for the treatment of chronic HCV patients not responding to previous treatment in the form of (Sofosbuvir and daclatasvir) combination regimen in Egyptian patients is extremely efficient and well-tolerated in both cirrhotic and non-cirrhotic patients (Child score < 8). The use of regimen showed maximum efficacy in SVR12 was (97.1%) over a period of 12 weeks with mild side effects (23.5%) mostly in the form of headache, fatigue, diarrhea and no deaths or serious adverse events were reported during treatment.

Recommendation

1. Study the effectiveness and safety of Velpatasvir containing regimens for the treatment of HCV coinfection with HIV or HBV.

2. Large-scale studies for HCC surveillance and post-treatment follow-up in cirrhotic patients.

Conflict of Interest

The authors state that they have no interests in conflict.

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الدراسة البيوكيميائية على الاستجابة لعلاج فيروس الكبد الوبائي سي (vosevi), (velpatasvir containing regimen)ب للمرضى الغير مستجيبين للعلاج في الفيوم- مصر

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تُستخدم العوامل المضادة للفيروسات ذات المفعول المباشر(DAAs) ، "وهي أدوية عن طريق الفم ، لعلاج عدوى فيروس التهاب الكبد الوبائي سي. حققت الأنظمة القائمة على DAA في جميع أنحاء العالم معدلات شفاء ممتازة ومعدل استجابة فيروسية مستدامة أعلى (SVR) من تركيبات العلاج السابقة المحتوية على الانترفيرون. لم يتم تحقيق SVR في حوالي 5٪ من مرضى التهاب الكبد C الذين يتناولون أدوية DAAs. فوكسيلابريفير / فيلباتاسفير / سوفوسبوفير (VOX / VEL / SOF) هو الخيار الأول لعلاج الخط الثاني للمرضى بعد فشل DAA سابق. لذلك ، كان الغرض من هذه الدراسة هو تقييم فعالية والأمان والتغيرات الكيميائية الحيوية لاستخدام نظام يحتوي على Velpatasvir (vosevi) لمدة 12 أسبوعًا في المجتمع المدروس.

شملت الدراسة الجماعية المحتملة 102 مريضاً فشلوا في العلاج بمركب (سوفوسبوفير وداكلاتاسفير). تم استقدام مرضى من مركز الكبد بتأمين الفيوم الصحي وتم إخضاعهم لنظام (SOF / VEL / VOX) تم تقييم الاختبارات المعملية قبل بداية العلاج ، 4 أسابيع ، 8 أسابيع ، نهاية العلاج ، و 12 أسبوعًا بعد العلاج.

أظهرت الدراسة أنه بعد 12 أسبوعًا من العلاج ، كان لدى 99 مريضًا (97.1٪) استجابة فيروسية كاملة بينما لم يصل 3 (2.9٪) مرضى إلى SVR12. بالإضافة إلى ذلك ، تم اكتشاف آثار جانبية طفيفة في 23.5٪ فقط بينما لم تظهر البقية أي آثار جانبية. أظهرت اختبارات وظائف الكبد أثناء العلاج وفي SVR12 تحسنًا ملحوظًا.

لذلك يعتبر فوسيفي Vosevi علاج فعال لمرضى التهاب الكبد C الذين يحتاجون إلى العلاج مرة أخرى في مصر مع أعراض جانبية خفيفة.