IS TREATMENT OF HEPATITIS C WITH CONTROLLED GENERIC DIRECT ACTING ANTIVIRAL DRUGS EFFECTIVE? AN EGYPTIAN EXPERIENCE

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INTRODUCTION

Oral DAAs have revolutionized the treatment of HCV with shorter treatment duration and higher rates of SVR, albeit being very expensive. Egypt has very high HCV prevalence and the cost of treatment is prohibitive. Here, we report real life treatment outcomes using affordable generic sofosbuvir (SOF) and daclatasvir (DCV) at Tahya Misr HCV Treatment Center in Luxor, Egypt.

METHODS

Patients aged 18-75 years and positive for HCV RNA were enrolled into the treatment program, while patients with advanced cirrhosis (CTP B&C), hepatocellular carcinoma, extrahepatic malignancy, uncontrolled diabetes and pregnancy were excluded.

Eligible patients were classified into two groups; Easy to treat (ET) (treatment naive, albumin ≥3.5 gm/dl, bilirubin ≤1.2 mg/dl, platelet count ≥150,000 cell/mm3, INR ≤1.2) and difficult to treat (DT) (interferon experienced, albumin <3.5 gm/dl, bilirubin >1.2 mg/dl, platelet count <150,000 cell/mm3, or INR >1.2).

ET patients were treated with SOF 400 mg plus DCV 60 mg once daily for 12 weeks. Ribavirin (RBV) 600 mg daily was added for DT patients. Patients who previously failed SOF-based regimens were treated with SOF/DCV/RBV for 24 weeks.

We analyzed the data of 522 patients treated at the center from June to September 2016. 12 patients (2.3%) did not complete treatment due to lack of adherence and 86 patients (16.5%) were lost to follow-up after finishing therapy.

RESULTS

Of the 424 patients included, 251 were males (59.2%). The mean age was 55.5±9.8 years. 389 patients (91.8%) were treatment naive, 15 patients (3.5%) were experienced to interferon and 20 patients (4.7%) to SOF-based regimens. 21.2% of the patients were cirrhotic. Six patients were positive for HBsAg with low HBV viral load.

262 patients (61.8%) were treated with SOF/DCV and 162 patients (38.2%) with SOF/DCV/RBV. 405 patients (95.5%) were treated for 12 weeks and 19 patients for 24 weeks.

SVR12 was achieved in 410 patients (96.7%), while 14 patients (3.3%) failed therapy. SVR was not affected by the different variables. SVR was similar in both ET & DT groups **(Table 1, Figure 1 & 2)**.

Side effects were reported in less than 10% and were mainly headaches, fatigue and nausea.

Table (1): *Comparison between SVR and non-SVR patients by different variables.*

		Total		SVR		Non-SVR		p value
		No	%	No	%	No	%	
Sex	Male	251	59.2%	244	97.2%	7	2.8%	0.48
	Female	173	40.8%	166	96.0%	7	4.1%	
Age	Range	19 - 78		19 - 78		33 - 70		0.82
	Mean ± SD	55.5 ± 9.8		55.5 ± 9.8		56 ± 11		
Treatment History	Naiive	389	91.8%	375	96.4%	14	3.6%	0.97
	Experienced	35	8.2%	35	100.0%	0	0.0%	
Treatment Type	Dual	262	61.8%	253	96.6%	9	3.4%	0.85
	Triple	162	38.2%	157	96.9%	5	3.1%	
Treatment Duration	12 weeks	405	95.5%	391	96.5%	14	3.5%	0.97
	24 weeks	19	4.5%	19	100.0%	0	0.0%	
Ultrasound	Non-cirrhotic	334	78.8%	323	96.7%	11	3.3%	0.98
	Cirrhotic	90	21.2%	87	96.7%	3	3.3%	
Transient Elastography (n=262)	F0	22	8.4%	21	95.5%	1	4.6%	0.84
	F0-1	58	22.1%	57	98.3%	1	1.7%	
	F1-2	41	15.7%	40	97.6%	1	2.4%	
	F 2-3	72	27.5%	69	95.8%	3	4.2%	
	F3-4	35	13.4%	35	100.0%	0	0.0%	
	F4	34	13.0%	33	97.1%	1	2.9%	
FIB4 Score	<1.45	164	38.7%	157	95.7%	7	4.3%	0.63
	1.45-3.25	178	42%	174	98%	4	2%	
	>3.25	82	19.3%	79	96.3%	3	3.7%	
HBsAg	Negative	418	98.58%	404	96.65%	14	3.35%	0.98
	Positive	6	1.42%	6	100.00%	0	0.00%	

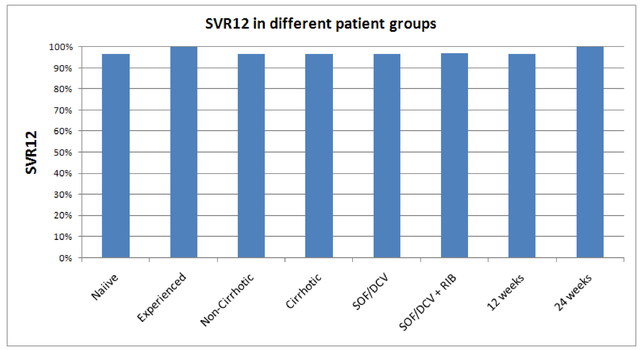

Figure (1): *Comparison between SVR and non-SVR patients by different variables.*

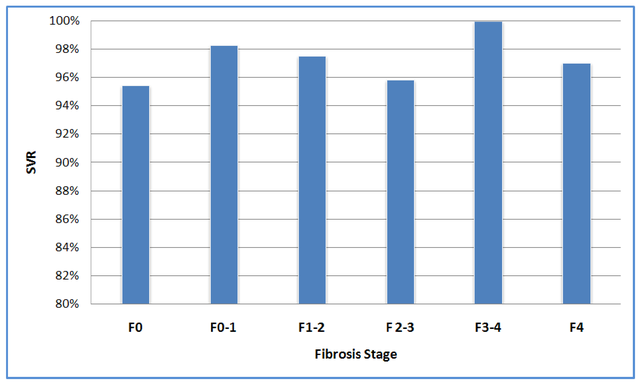

Figure (2): *SRV rate according to fibrosis stage by transient elastography (n= 262; p =0.84).*

CONCLUSION

1) The combination of SOF/DCV is highly effective in curing HCV GT4.
2) Applying standard protocols, SVR rate in real life is similar to clinical trials.
3) Generic SOF/DCV is safe and as effective in treating HCV GT4 as brand DAAs.
4) In summary, guaranteeing the quality of generic DAAs will impact HCV therapy in low income countries.

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