569

95% SVR Rates Using Imported Generic DAAs for Patients With Hepatitis C

Andrew Hill[1], Giten Khwairakpam[2], James Wang[3], Sergey Golovin[4], Julia Dragunova[5], Rachel Smith[6], Vicky Houghton-Price[6], Roxanna Korologou-Linden[7], Anton Pozniak[1], Greg Jefferys[8], James Freeman[9].
[1]St Stephens AIDS Trust, Chelsea and Westminster Hospital, London, UK. [2]TREAT Asia/amfAR, Bangkok, Thailand. [3]Ci Run Health Information Consulting Co. Ltd., Kunming, China. [4]International Treatment Preparedness Coalition, St Petersburg, Russia. [5]International Treatment Preparedness Coalition and GEPATITKA Community, St Petersburg, Russia. [6]Metavirology Ltd. London, UK. [7]Faculty of Medicine, Imperial College, London, UK. [8]University of Tasmania, Hobart, Australia. [9]Sandy Bay Medical Nephrology Sandy Bay Australia.

Presented at CROI 2017, Seattle, February 13–16, 2017

St Stephen's AIDS TRUST

Correspondence to:
Dr Andrew Hill PhD
St Stephen's AIDS Trust
Chelsea Chambers
262a Fulham Road
London SW10 9EL
Tel:+44 7834 364 608
Email: microhaart@aol.com

Background

Russia, China, countries in SE Asia and in Eastern Europe are not included in voluntary license agreements, and prices of DAAs in these countries are very high. An increasing number of people in these regions are treating their HCV infection with generic drugs produced in India, China, Bangladesh or Egypt and legally imported. This analysis assessed the efficacy of these generic DAAs.

Methods

1150 patients sourced generic versions of sofosbuvir (SOF), ledipasvir (LDV), daclatasvir (DCV) and velpatasvir (VEL) from suppliers in India, Bangladesh, China and Egypt via established Buyers Clubs. The choice of DAAs and the length of treatment were determined based on baseline RNA levels, HCV Genotype and stage of fibrosis. Patient HCV RNA levels were evaluated pre-treatment, during treatment, at end of treatment (EOT) and then for SVR 4, 12, and 24 weeks.

Results

Overall 1150 patients submitted results (224 from an Australian Buyers Club, 154 from a Chinese Buyers Club, 224 from a Russian Buyers Club, 100 from a South-East Asian Buyers Club and 448 from a second Australian Buyers Club). Of the 1150 patients treated, 100 received SOF (65 with RBV), 502 received SOF/LDV (57 with RBV), 545 received SOF/DCV (81 with RBV) 2 received SOF/LDV/DCV (0 with RBV) and 1 received SOF/VEL (with RBV). Overall, the patients were 60% male with a mean age of 44.4 years; 56 % were Genotype 1, 18% cirrhotic and a mean baseline HCV RNA was 6.8 log10 IU/mL. A rapid virological response (RVR) was observed in 91% (52/57) of patients treated with SOF(+/-RBV), 84% (165/196) of the patients treated with SOF/DCV and 81% (135/167) of the patients treated with SOF/LDV*. Based on currently available data, the percentage of patients with HCV RNA<LLoQ was 98% (667/678) at end of treatment (EOT), 95% (538/569) at SVR4 and 90% (454/503) at SVR12.

Conclusions

In this analysis, treatment with legally imported generic DAAs achieved high rates of HCV RNA undetectability at the end of treatment, and SVR in all patients evaluated to date. The efficacy observed is similar to Phase 3 trials of the branded medicines. Mass treatment with the current generic DAAs is a feasible and economical alternative route of accessing curative DAA's, where the high-prices for branded DAA's prevent access to treatment.

*Note: This does not include data from one Australian buyers club as aggregated data was not available by treatment regimen or by genotype.

Table 1: Baseline Characteristics

Patients	SOF & SOF/RBV N=100	SOF/DCV N=545	SOF/LDV N=502
% Male	79 % (79/100)	57 % (321/545)	57 % (288/502)
% Cirrhosis	16 % (16/100)	20 % (111/545)	16 % (78/502)
% GT 1	35 % (35/100)	31 % (168/545)	87 % (439/502)
% GT 3	46 % (46/100)	58 % (314/545)	4 % (19/502)
+ RBV	65 % (65/100)	7 % (81/545)	5 % (57/502)
12 weeks or less*	41 % (41/100)	66 % (363/545)	79 % (398/502)
24 weeks or more*	38 % (38/100)	21 % (114/545)	11 % (55/502)

Table 2: HCV RNA <25 IU/mL at RVR, EOT and SVR*

Patients	SOF & SOF/RBV N=97	SOF/DCV N=338	SOF/LDV N=264
RVR	91 % (52/57)	84 % (165/196)	81 % (135/167)
EOT	98 % (39/40)	98 % (121/123)	97 % (102/105)
SVR4	100 % (30/30)	100 % (104/104)	97 % (109/112)
SVR12	91 % (21/23)	96 % (76/79)	100 % (79/79)

Table 3: Generic manufacturers of treatments purchased by patients

Company	SOF	DCV	LDV
Chinese API**	451/1150 (39%)	237/547 (43%)	239/504 (47%)
Cipla	230/1150 (20%)	87/547 (16%)	99/504 (20%)
Hetero	194/1150 (17%)	103/547 (19%)	66/504 (13%)
Natco	49/1150 (4%)	16/547 (3%)	18/504 (4%)
Mylan	47/1150 (4%)	9/547 (2%)	12/504 (2%)
Zydus	29/1150 (3%)	24/547 (4%)	2/504 (<1%)
Other***	107/1150 (9%)	48/547 (9%)	58/504 (11%)
No data	43/1150 (4%)	23/547 (4%)	10/504 (2%)

**Chinese API supplier not specified. Compounded by Australian pharmacies. ***Others: Mesochem, Incepta, Strides Arcolab, Marcyrl, Emcure, Sun Pharma, Beacon, Aug Pharma, Pharmed Healthcare, Grateziano, JSC North Star, JSC Vertex, Dr. Reddys. Note: This table includes the manufacturers used by 2 patients taking SOF/DCV/LDV.

Figure 1: Patients by genotype

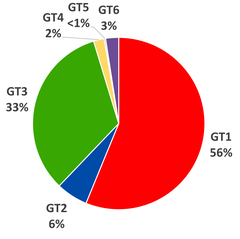


Figure 2: Fibrosis scores of patients

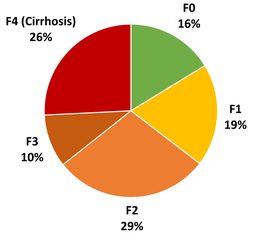


Figure 3: SVR4 responses by genotype

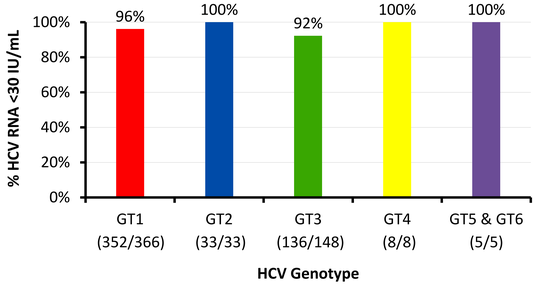


Figure 4: SVR12 responses by genotype*

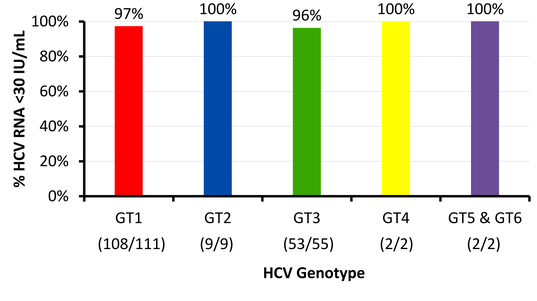
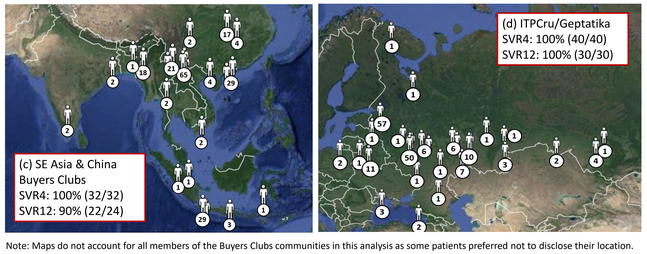


Figure 5: Locations of patients; (a) FixHepC community; (b) HepC Treatment Without Borders community; (c) South East Asia & China buyers clubs community; (d) ITPC EECA, Gepatitka community



Note: Maps do not account for all members of the Buyers Clubs communities in this analysis as some patients preferred not to disclose their location.