Boceprevir for the treatment of chronic hepatitis C in HIV co-infection

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Background

Co-infection of hepatitis C virus (HCV) and HIV is associated with excess morbidity and mortality. Recently new treatments for HCV have been licensed. Prior to licensing boceprevir was available to HIV infected individuals co-infected with HCV as part of an expanded access programme (EAP).

Method

We reviewed the outcomes of individuals who received boceprevir within a designated EAP with an interim analysis at treatment week (TW) 16.

Key inclusion criteria:
-≥ 18 years old
-Genotype 1 HCV
-Previously failed treatment for HCV
-Compensated liver disease with bridging fibrosis or cirrhosis

All individuals were initiated on 4 weeks of pegylated interferon and weight based ribavirin then triple therapy with boceprevir for 44 weeks.

Results

5 patients (n1-n5) were recruited into the boceprevir EAP (4 male and 1 female). All were on antiretroviral therapy (ARV) for treatment of HIV, n5 switched ARV at TW8 to darunavir/ritonavir monotherapy due to a decline in renal function and raised bilirubin.

Table 1. ARV therapy, CD4 count and HIV viral load of individuals recruited into boceprevir EAP at TW0 and TW16

	ARV combination	CD4 TW 0	CD4 TW 16	VL TW 0	VL TW 16
n1	RAL/TFV/FTC	368	202	<40	<40
n2	DRV/RTV/3TC/TFV	245	166	<40	<40
n3	DRV/RTV/TFV/FTC	742	562	<40	<40
n4	DRV/RTV/MVC/3TC	222	292	<40	<40
n5	TAZ/RTV/TFV/FTC	688	351	<40	<40

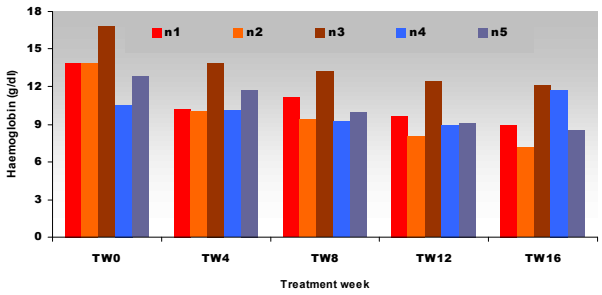
4/5 achieved a greater than 1 log drop in HCV PCR after the lead in phase. n4 stopped boceprevir at TW8 because of infection related neutropenia. 4 individuals had a neutrophil count below 1 (10^9/l) with 2 requiring treatment with G-CSF.

Table 2. Analysis of HCV PCR results from TW0 to TW16

	HCV PCR (IU/ml)				
	TW 0	TW 4	TW 8	TW 12	TW 16
n1	3842790	85738	10172	<15	<15
n2	1947149	607039	<15	<15	<15
n3	117140	10088	<15	<15	<15
n4	9283263	5756	<15	<15	<15
n5	11190303	75634	<15	<15	<15

4 individuals had a haemoglobin drop below 10g/dl and required treatment with epoetin. 3 of these individuals also required dose reduction of ribavirin. Commonly reported side effects were depression (4/5), dysgeusia (4/5) , fatigue (4/5) and anaemia (4/5).

Figure 1. Analysis of haemoglobin results from TW0 to TW16



Conclusion

In this small cohort of co-infected patients who had previously failed treatment for HCV, boceprevir was associated with a high rate of initial treatment response and toxicity.

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