Hepatitis C virus treatment response to sofosbuvir/ledipasvir among adolescents coinfected with HIV and HCV: Real world data from Ukraine

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BACKGROUND

- An estimated 3.26 million children and adolescents worldwide have chronic hepatitis C virus (HCV) infection.
- Children with HIV (human immunodeficiency virus)/HCV coinfection have more progressive liver disease than their HCV monoinfected counterparts, and lower success with pegylated-interferon/ribavirin treatment.
- Although Direct Acting Antiviral (DAA) regimens are now approved for HCV treatment in children aged as young as 3 years, **there are limited real world data on treatment of HIV/HCV coinfected children and adolescents**.
- Here, we describe treatment outcomes of HIV/HCV coinfected adolescents treated with sofosbuvir/ledipasvir (SOF/LED) in Ukraine.

METHODS

- HIV/HCV coinfected children and adolescents treated with any DAAs were identified from the ongoing **Ukraine HIV Paediatric Cohort Study** which was established in 2011.
- Children and adolescents aged up to 18 years, with confirmed HIV infection and HCV RNA+ve (regardless of mode of acquisition) being cared for at 8 participating HIV centres across Ukraine were included in this analysis.
- Standardised data collection forms are used to collect data on routine clinical care. Descriptive and summary statistics were used to analyze population characteristics and sustained virologic response (SVR) rates, defined as absence of quantifiable HCV RNA in serum 12 weeks after the end of therapy.

Patient	Gender	Age (yr) at HIV diagnosis	Age (yr) at HCV diagnosis	HCV genotype	Age (yr) at HCV treatment start	Diagnosis of TB	ALT (U/L)	ALT (U/L)	HCV RNA copies/ml	HCV RNA copies/ml	Treatment outcome
							before treatment	after treatment	before treatment	after treatment	
1	Male	11	13	1b	17	-	73.1	28.4	20300000	92	SVR12
2	Male	2	2	1b	14	-	123	18	183466	Undetectable	SVR12
3	Male	1	2	1b	16	-	74	32.7	14620	Undetectable	SVR12*
4	Female	1	9	1b	13	EPTB#	57.5	14.8	245000	Undetectable	SVR12

* early response to treatment at 9 weeks
\# extrapulmonary tuberculosis

RESULTS & CONCLUSIONS

- Four HIV/HCV coinfected adolescents receiving DAA treatment were identified (table), **all treated with sofosbuvir / ledipasvir SOF/LED (400/90mg)**. The purported mode of HIV/HCV transmission in all 4 patients was vertical, 3 patients were male and all had HCV genotype 1b. First SOF/LED treatment was initiated in December 2017.
- All patients were HCV treatment naïve, all were on HIV treatment (efavirenz/emtricitabine/tenofovir) with undetectable plasma HIV viral load (<20 copies/ml) at start of SOF/LED and continued the same ART regimen throughout HCV treatment.
- Two patients had received 6-month isoniazid preventive therapy for tuberculosis prior to initiating treatment with SOF/LED.
- All patients were assessed with liver ultrasound prior to starting SOF/LED: all showed changes in liver parenchyma and increased liver echogenicity.
- Duration of the SOF/LED therapy was at the discretion of the treating physician and all 4 adolescents were treated for 13 weeks. All patients had pre-treatment alanine aminotransferase (ALT) levels >40U/L, with average ALT levels decreasing from 81.9 U/L to 23.5 U/L after treatment.
- No adverse events, treatment discontinuations or dose adjustments for SOF/LED were documented. **All 4 adolescents achieved SVR12**. One patient had early treatment response with undetectable HCV RNA at 9 weeks of SOF/LED.

Children and adolescents with HIV/HCV co-infection should be a priority group for DAA treatment and HCV microelimination. This real-world data from Ukraine shows that SOF/LED was effective and well tolerated in HIV/HCV coinfected adolescents.

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