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Multicenter study on outcome of HCV treatment using ledipasvir/sofosbuvir combination in Mongolian population

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Background: The incident of liver cancer in Mongolia is generally caused by HBV and HCV, and is 7 times higher than that of world's average. HCV, the most prevalent cause of HCC in Mongolia, is number one public health issue. Mongolia is one of the first countries that registered Ledipasvir/Sofosbuvir (LDV/SOF) regimen from developing countries. By the support of Access program run by Gilead Sciences, USA, we started HCV treatment program from January 2016.

Materials & Method: We followed and evaluated treatment outcome of patients with HCV infection using combination of 90 mg ledipasvir/400 mg sofosbuvir (manufactured by Gilead Science) in 937 treatments naïve and 83 treatment experienced patients. All patients were treated with LDV/SOF for 12 weeks and, their treatment was evaluated by quantitative HCV-RNA assays prior and W (week) 4 and W12 of treatment. Sustained virological response (SVR) after 12 weeks treatment was assessed. Virus genotype analysis using cDNA microarray, liver enzymes, CBC and drug related adverse events were assessed in every patient. The laboratory tests were conducted at National Center of Communicable Diseases, Happy Veritas Laboratories and other provinces' health care center.

Results: We conducted largest ever (415/1020) HCV genotype (GT) distribution study in Mongolian chronic HCV patients. 96.6% (n=401) of assessed patients were GT1b; 0.7% (n=3) were GT2; 0.2% (n=1) were GT1a and b; 0.9% (n=4) were GT1b and 2; 0.5% (n=2) were GT1b and 6; 0.2% (n=1) were GT5 and 0.2% (n=1) were GT1b and 80k mutants respectively. 992/1020 (97.3%) patients achieved SVR12W, 28 (2.7%) patients who did not achieve SVR12W were all genotype 1b. Median ALT level significantly dropped during treatment from 95.5±84.1 IU/L to 27.2±18.6 IU/L and slightly increased by the end of treatment 42.9±17.4 IU/L. Total of 39 adverse events were observed in 595/1020 patients (58.3%). Single adverse events were observed in 401/1020 (39.3%) whereas 2 and more events were observed in 194 (19%) patients respectively. Unreported adverse events such as partial facial palsy, AFP (alpha-fetoprotein) increase, melasma were observed.

Discussion & Conclusion: Treatment of HCV in Mongolia using all-oral dual DAA was divided into 3 phases due to shortness of drugs and logistics arrangements. We could include only stage-one patients in this study. We achieved 97.3% SVR12W for 3 months treatment with LDV/SOF this time. But viral relapse must be determined repeatedly at weeks 24 and 48 post treatment. All viral relapses (n=14) and non-responders (n=14) were GT1 in our study. According to HCV genotype assessment, there was no difference in treatment outcomes between patients who had different genotypes. Genotype distribution of Mongolian patients confirmed the results of other smaller studies. HCV RNA clearance during treatment was no different than clinical trials, but the slight increase of ALT by the end of treatment was commonly observed. It might have happened due to rebound of immune reaction after clearance of HCV or a drug induced effect.

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