A new drug program for chronic hepatitis with interferon-free therapy (B.71) was introduced in Poland in July 2015. Since November 2015 the N=135 – 245 patients were treated. The average log10 HCV load (SVR24) since the end of treatment was 2.18 (4%).

The objective of the study was to evaluate response of patients with chronic hepatitis C to OBV/PTV/DSV treatment in real-life settings, as is the national drug program.

Methods

Data were collected on patients treated with OBV/PTV/DSV in RV/R enrolled to drug program B.71. The study was carried out in two stages. In June 2016 basic characteristics, previous treatment and end of treatment response (ETR), including reasons for early termination were collected retrospectively. In the second stage (September - October 2016) the sustained virologic response after 12 weeks (SVR12) and after 24 weeks (SVR24) since the end of treatment were added.

The study sample comprised all patients enrolled in the drug program between 1st October 2015 and 31st January 2016 in 7 non-randomly selected medical centers. The centers of different size, located across the country had also different number of patients enrolled in the program. SVR12 assessment was performed by default only in one center, and only those SVR12 results were included in the study. In case of one center, data for only a part of the sample (113 out of 143) was collected at the time of the database lock. Some observations lack SVR24, as in some cases (e.g. 24-week therapy) the results of the HCV RNA tests were not available on the day of the database lock. Complete results will be presented in the final report. Data of study participants were collected and analyzed on the day of database lock. Complete results will be presented in the final report. Data of study participants were collected and analyzed retrospectively. In the second stage (September - October 2016) the sustained virologic response after 12 weeks (SVR12) and after 24 weeks (SVR24) since the end of treatment were added.

Response was defined by the following outcome parameters: treatment withdrawal (treatment cessation due to adverse event), death (rate of death in the study was 0.07% or 1 in 147 patients), no data about SVR24 (3% of patients), patient loss in follow-up (9% of patients), 3-months early discontinuation (9% of patients), intolerance (6% of patients), nonmedical reasons (2% of patients), 6-months early discontinuation (5% of patients). The summary of prior interference therapy outcome is presented in Table 2.

The average of patients at baseline (day of recruitment to the drug program) was 54 ranging from 21 to 90. The average log10 HCV load was 5.69 and was distributed normally (Figure 1). Most patients (51%) had cirrhosis (F4 on the META4R scale). Genotype 1 was observed in 90% of the sample. The most frequent interferon null genotype among patients who performed the genotyping was C/T (79%, 59%). Patients to whom the genotype (n=268) reported comorbidity, the most common being hypertension (31%) and diabetes (12%). The list of most frequently occurring comorbidities is presented in Table 2.

The average initial dose of Modena was 1045 mg (n=265), with 124 patients (47%) taking 1000 mg per day. 104 (39%) achieving 1200 mg and 52 (12%) using 800 mg. During treatment Modena was stopped in 3 patients, and Modena dose was reduced in another 27 cases (average dose reduction of 276 mg). 7 patients had Modena dose increased (on average by 257 mg) throughout the treatment within the drug program.

Out of 474 patients who completed treatment 463 (97%) had ETR and 11 (2%) were treatment failures. The results of the trial reported 98% effectiveness in the same subpopulation. The effectiveness of OBV/PTV/DSV treatment was 93% (94% SVR24). The results of the study are comparable to RCT results. For example, SVR24 for patients with no prior treatment and genotype 1b was achieved by 94% (196/208), while the MALACHITE I clinical trial reported 98% effectiveness in the same subpopulation.