Conclusion Our results demonstrate that with simple support SVR rates in the active drug user group can be achieved which are comparable with non IDU infected individuals. Intravenous drug use should not be seen as a barrier to treatment of individuals with HCV.

P84 LOW RATES OF NUCLEOS(T)IDE-ASSOCIATED ADVERSE EVENTS IN THE LONG-TERM EXPERIENCE WITH ENTECAVIR

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Introduction In Phase III studies evaluating treatment of chronic hepatitis B (CHB), entecavir demonstrated superior efficacy compared to lamivudine and a comparable safety and tolerability profile. Long-term safety data from the rollover study ETV-901 are reviewed, focussing on adverse events (AEs) with a potential nucleos (t)ide association.
Method Long-term cumulative safety and tolerability results are based on investigator-reported AEs, regardless of causal relationship.
Results Median exposure to entecavir in ETV-901 was 168 weeks. Of the 1045 treated patients, 402 (38%) had received entecavir for =5 years at the time of analysis. Also, 488 (47%) patients had additional prior entecavir exposure from Phase II or III participation. Baseline characteristics were: mean age 41 years; 804 (77%) male, 539 (52%) Asian, and 480 (46%) Caucasian. The most common AEs (=10%) were upper respiratory tract infection, headache and nasopharyngitis. On-treatment alanine aminotransferase (ALT) flares were reported in 3% of patients. The cumulative rate of serious AEs was 15%. Discontinuations due to AEs were 1% (n=13), and generally (n=11) occurred during the first 2 years of ETV-901. Selected AEs with a potential nucleos(t)ide association are described below.

Abstract P84 Table 1 Results

Investigator-reported adverse events (all grades; unrelated and related to entecavir)*	Median exposure 168 weeks N=1045, n (%)
Elevated lipase†	21 (2)
Pancreatitis	3 (<1)
Blood creatinine increase	8 (<1)
Hypophosphataemia†	5 (<1)
Creatine phosphokinase increase†	2 (<1)
Myalgia	50 (5)
Muscular weakness	4 (<1)
Neuropathy-related adverse events (hypo-, hyper-, paraesthesia, polyneuropathy)	39 (4)
Lactate increase† or bicarbonate decrease	6 (<1)

*Multiple adverse events per individual patient are possible.
†No prospective testing for laboratory parameter (reactive only).

Conclusion Entecavir is a safe and well-tolerated treatment for patients with CHB and compensated liver disease. Long-term administration of entecavir was associated with low rates of serious AEs, discontinuations due to AEs and ALT flares. Spontaneous reports of AEs potentially associated with nucleos(t)ide use occurred at low rates.

P85 COGNITIVE SYMPTOMS IN CHRONIC HEPATITIS C INFECTION ARE ASSOCIATED WITH IMPAIRED COGNITIVE TEST PERFORMANCE BUT ARE UNRELATED TO PERIPHERAL MARKERS OF CELLULAR IMMUNE ACTIVATION

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Introduction Patients with hepatitis C virus (HCV) infection frequently complain of "brain fog" and impaired cognitive performance is well described in some patients. A direct virological effect of HCV on the CNS and a central effect of peripheral inflammation have both been hypothesised as mechanisms.
Aim We aimed to determine whether cognitive symptoms are associated with markers of peripheral immune activation and objectively measured cognitive impairment.
Method 53 HCV patients with mild liver disease and 19 healthy controls, matched for age, sex, education and ethnicity, underwent computer-based cognitive testing (United BioSource, UK). The Medical Outcomes Survey Cognitive Function Scale (MOSCog) was used to assess cognitive symptoms. The Fatigue Impact Scale (FIS) and Beck Depression Inventory (BDI) were also employed. Serum neopterin was measured by ELISA, beta-2-microglobulin by nephelometric assay.
Results 19 (36%) HCV patients had MOSCog<75 and formed the symptomatic group and were compared to asymptomatic patients and healthy controls using ANOVA/Kruskal–Wallis tests as appropriate. Symptomatic HCV patients demonstrated significantly worse performance on memory (p=0.013) and attention tests (p=0.008) compared to asymptomatic patients and controls. Neopterin and beta-2-microglobulin levels were higher in HCV patients as a whole (p=0.002) but there were no significant differences between symptomatic and asymptomatic cases. In addition there were no differences in age, gender, ethnicity, education, alcohol intake, history of injection drug use, viral load, genotype and ALT between groups. Symptomatic patients reported worse scores on the BDI and FIS compared to asymptomatic patients (p<0.001) but there were no associations with neopterin and beta-2-microglobulin levels.
Conclusion In summary, important cognitive symptoms in over 1/3 of patients were associated with impaired performance on objective cognitive testing but were unrelated to markers of immune activation. It is unclear whether depression is a primary cause or occurs together with impaired cognition as a result of a direct effect of HCV on the brain.

P86 DOES GENOTYPE PREDICT RESPONSE TO TREATMENT IN CHILDREN PERINATALLY INFECTED WITH HEPATITIS B VIRUS

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Introduction Hepatitis B Virus (HBV) genotype is now thought to correlate to outcome and response to treatment.
Aim To compare viral genotype with treatment response in children infected perinatally with HBV, who had been treated with subcutaneous Interferon alpha2b (IFN) with or without Prednisolone priming (Pred/IFN), oral antiviral drugs (Lamivudine or Adefovir).
Method All children who took part in the clinical trials in this unit since 1990 were included. The hepatitis B genotypes were determined using a commercial line probe assay (InnoLipa), which was validated against direct sequencing.
Results 70 children were recruited to clinical trials, 68 of whom had genotype analysis. 5 children had more than one course of therapy: The genotype results correlated with the geographical origin of the