

ALCOHOLIC AND NONALCOHOLIC FATTY LIVER DISEASE

HEPTRAL® (ADEMETIONINE) IN PATIENTS WITH INTRAHEPATIC CHOLESTASIS DUE TO CHRONIC ALCOHOLIC LIVER DISEASE: RESULTS OF A MULTICENTRE OBSERVATIONAL STUDY IN INDIAN PATIENTS

Ravi Shankar[†], Tina Singh[†], Gourdas Choudhuri[†]

*Division of Medical Sciences, Abbott India Limit, 3-4 Corporate Park, Sion-Trombay Road, Mumbai, Maharashtra, India, and

[†]Division of Gastroenterology and Hepato-biliary Sciences, Fortis Healthcare, Gurgaon, Haryana, India

Background and Objectives: The observational study was aimed at assessing the effectiveness and tolerability of Heptral® (brand of ademetonine 1, 4-butanedisulfonate) in Indian patients presenting with intrahepatic cholestasis (IHC) due to chronic alcoholic liver disease (ALD). The study also aimed at understanding the prescribing practices of physicians as well as the profile of patients being prescribed Heptral®.

Methods: This prospective observational study included 250 patients across 21 study sites. The assessments of health-economic parameters (patient visits to healthcare services, number of days in hospital, and number of days off work in preceding six weeks), liver biochemistry [serum total bilirubin (STB), serum conjugated bilirubin (SCB), serum alkaline phosphatase (ALP), serum alanine transaminase (ALT), serum aspartate transaminase (AST) and serum γ -glutamyl transpeptidase (γ GT)], signs and symptoms of IHC (fatigue, jaundice, and pruritus) were performed at two visits, i.e., at baseline and after six weeks of Ademetonine treatment. Ademetonine was prescribed as part of the routine medical treatment as per the local label and not as a study intervention.

Results: Of the 243 patients included in the analysis population, cirrhosis was present in 42.8% (104); 72% (175) were heavy drinkers, i.e., taking four or more drinks per day. Ademetonine administration resulted in significant ($P < 0.0001$) reduction in health-economic burden (number of days off work [-4.28 days], number of visits to healthcare services as outpatient [-0.72], and number of days in hospital [-1.42 days]), levels of

biochemical markers [mean reduction in STB by 3.19 mg/dL, SCB by 2.41 mg/dL, ALP by 73.38 IU/L, ALT by 45.36 IU/L, AST by 64.05 IU/L and γ GT by 100.96 IU/L ($P < 0.0001$)], signs and symptoms of IHC [At baseline, fatigue, jaundice and pruritus were reported by 80.2% (195/243), 81.1% (197/243), and 36.2% (88/243) patients respectively. At visit 2, these proportions decreased to 38% (92/243), 56% (136/243) and 10% (24/243) respectively ($P < 0.05$)]. Beneficial effects were seen irrespective of presence/absence of cirrhosis, drinking patterns (heavy or not heavy drinkers), varied dosage of Heptral®, and use of concomitant medications. The treatment was well tolerated. Four (1.6%) patients experienced SAE which resulted in death. All these fatal SAEs were judged as events not related to the study drug, by the investigators.

Conclusions: Administration of Heptral® in patients with ALD and IHC resulted in significant improvement in burden of disease, laboratory markers, signs and symptoms of cholestasis.

Corresponding author: Ravi Shankar.

Email: r.shankar@abbott.com

GLYCINE STABILIZE THE TISSUE FATTY ACID COMPOSITION IN AN EXPERIMENTAL MODEL OF ALCOHOL-INDUCED HEPATOTOXICITY

Senthilkumar Rajagopal

Department of Zoology, Osmania University, Hyderabad, Andhra Pradesh, India

Background and Aim: The aim of the present study was to investigate the effect of the administration of glycine, a non-essential amino acid on tissue fatty acid composition in experimental rats.

Methods: Liver cell damage was induced by the administration of ethanol (7.9 g/kg b.w.) for 30 days by intragastric intubation. Control rats were given isocaloric glucose solution. Glycine was subsequently administered at a dose of 0.6 g/kg bodyweight every day by intragastric intubation for the next 30 days.