

Abstract

AIMS/BACKGROUND:

Current therapy for chronic hepatitis C virus (HCV) infection is based on the administration of interferon alpha (IFN) alone or in combination with other anti-viral agents. However, such therapy is effective in only a minority of selected patients. Long-term ursodeoxycholic acid (UDCA) treatment has been reported to improve liver function and structure especially in cholestatic disorders. We investigated the effect of long-term UDCA treatment on liver function in respect to the severity of chronic liver disease and HCV genotypes.

METHODS:

Forty-five patients with non-cholestatic laparoscopy-biopsy proven HCV-associated chronic hepatitis (n=16) or cirrhosis (n=29) who had not responded to, or were unsuitable for IFN, were randomly assigned to receive UDCA (600 mg/day; n=23) or no therapy (n=22) for 12 months. At entry, all patients were evaluated by means of conventional and quantitative liver function tests (LFTs), including galactose elimination capacity and antipyrine clearance, HCV antibodies, HCV-RNA and HCV genotypes. LFTs were measured at 6 and at 12 months, whereas HCV-RNA was determined again after treatment.

RESULTS:
Baseline characteristics were comparable in the two study groups. Long-term UDCA therapy was well tolerated. Based on the analysis of variance, there was a significant decrease in serum transaminase, LDH and GGT levels in UDCA treated patients. By contrast, the activities of these enzymes increased in untreated patients, with AST levels reaching statistical significance only. Statistical analysis also showed that the improvement in biochemical markers was more pronounced in UDCA treated patients with liver cirrhosis than in those with chronic hepatitis but was similar in patients with HCV genotype 1b and non-1b. However, HCV-RNA was positive in all patients after treatment. Quantitative LFTs remained, on average, stable over the 12 months of the trial in all groups.

**CONCLUSIONS:**

Long-term UDCA treatment is well tolerated in patients with HCV-associated chronic liver disease. The effect appears to be greater in cirrhotics than in patients with chronic hepatitis but is independent of HCV genotypes. Thus, long-term UDCA treatment, despite the absence of an anti-viral effect, seems beneficial in reducing disease activity in patients with chronic hepatitis or cirrhosis who are unsuitable for IFN therapy.

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