

Severe hepatotoxicity following ingestion of Herbalife[®] nutritional supplements contaminated with *Bacillus subtilis*[☆]

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Background/Aims: Nutritional supplements are widely used. Recently, liver injury after consumption of Herbalife[®] preparations was reported but the underlying pathogenesis remained cryptic.

Methods: Two patients presented with cholestatic hepatitis and pruritus, and cirrhosis, respectively. Viral, alcoholic, metabolic, autoimmune, neoplastic, vascular liver diseases and synthetic drugs as the precipitating causes of liver injury were excluded. However, both patients reported long-term consumption of Herbalife[®] products. All Herbalife[®] products were tested for contamination with drugs, pesticides, heavy metals, and softeners, and examined for microbial contamination according to standard laboratory procedures. Bacteria isolated from the samples were identified as *Bacillus subtilis* by sequencing the 16S rRNA and *gyrB* genes.

Results: Causality between consumption of Herbalife[®] products and disease according to CIOMS was scored “probable” in both cases. Histology showed cholestatic and lobular/portal hepatitis with cirrhosis in one patient, and biliary fibrosis with ductopenia in the other. No contamination with chemicals or heavy metals was detected, and immunological testing showed no drug hypersensitivity. However, samples of Herbalife[®] products ingested by both patients showed growth of *Bacillus subtilis* of which culture supernatants showed dose- and time-dependent hepatotoxicity.

Conclusions: Two novel incidents of severe hepatic injury following intake of Herbalife[®] products contaminated with *Bacillus subtilis* emphasize its potential hepatotoxicity.

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Keywords: Drug-induced hepatitis; Food supplement; Herbal medicine; Herbalife; Weight reduction; Hepatotoxicity

1. Introduction

Widespread use of nutritional supplements containing vitamins, antioxidants, trace elements, proteins,

amino acids and herbal components has been recorded both in the US [1] and Europe [2,3]. Consumers turn to such products for presumed benefits regarding enhanced physical performance during sports activities, disease prophylaxis, improvement of nutritional status, and, particularly, weight reduction [2–4]. Consequently, dietary weight loss products have become a multi-billion market [5], and although not recommended for losing weight by nutrition expert panels [6,7], their long-term use without medical consultation is frequent [8]. Strong evidence supporting health advantages from these weight loss remedies is lacking and the significant costs

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