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Effects of Nutraceutical Epatrex on Hamaguchi Score in Subjects with Non-Alcoholic Fatty Liver Disease: A Statistical Modeling Analysis

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Abstract

Background: Epatrex is a nutraceutical compound for the treatment of Non-Alcoholic Fatty Liver Disease (NAFLD). It is formulated as a three-layer tablet containing *Lactobacillus casei* (LC-XCAL), silymarin/silybin and chromium nicolinate. The safety and efficacy of Epatrex *vs*. placebo has already been investigated in the REVEAL clinical trial. The results of the REVEAL study clearly demonstrated that the investigated nutraceutical was safe. Nevertheless, no clear differences of Epatrex over placebo with respect to blood markers of hepatic inflammation could be detected, suggesting that alternative biomarkers might be evaluated for a more comprehensive understanding of Epatrex's effects. To date, Epatrex effects have not been evaluated in relation to Ultrasound (US) imaging based biomarkers, such as the score introduced by Hamaguchi for the assessment of liver steatosis.

Objectives: In the present study we used the REVEAL study data to conduct statistical analyses. Assuming that the Hamaguchi score might be more sensitive than blood markers in detecting changes in liver steatosis, the objective of our analyses was to i) assess Epatrex effects on the Hamaguchi score endpoint and ii) investigate the impact of study design as well as patient-specific characteristics known to potentially affect placebo response. The results of these analyses indicate that the Hamaguchi score is sensitive to treatment period, alcohol consumption and patient waist circumference.

Conclusions: Our findings provide insights on how to improve clinical trial design and represent a first step toward a mechanistic understanding of Epatrex effects.

Keywords: Probiotics; NAFLD; REVEAL study; Epatrex; Hamaguchi score; Cumulative ordinal logistic regression

Introduction

Non-Alcoholic Fatty Liver Disease (NAFLD) is characterized by accumulation of lipids in hepatocytes at a percentage greater than 5% of the total number of cells [1]. This disease is similar to what is observed in chronic alcohol users, but occurs in patients with significant alcohol intake (<20 g of alcohol per day). NAFLD is currently considered the most common hepatic disease in Western countries, with prevalence from 5.7%-30% in the general population, while in obese patients the prevalence is much higher and ranges from 50%-90% [2-5]. Some studies have also shown a gender-based difference in the prevalence of the disease, with greater incidence in men (2-3 times higher) among younger patients and higher prevalence in women among patients older than 60 years of age [6]. NAFLD progression may lead to Nonalcoholic Steatohepatitis (NASH) and finally to liver cirrhosis, which is associated with increased risk of tumor and other complications [7].

Until the early 2000s, liver biopsy was the most cost-effective and sensitive test in patients with NAFLD for exclusion of steatohepatitis and its possible complications. However, due to ethical concerns, needle biopsy could not be performed as a screening method to detect NAFLD in the general population. To face this problem, Hamaguchi and colleagues were looking for a reliable noninvasive method for early detection of NAFLD and in 2007 proposed a new diagnosis criterion by scoring liver ultrasonographic findings [8]. They also analyzed the sensitivity and specificity of the new score and obtained significant results, 91.7% for sensitivity and 100% for specificity, paving the way to its adoption as a noninvasive method in the detection of NAFLD. A recent study confirmed the greater accuracy of ultrasound-based techniques with respect to biochemical indexes, finding Hamaguchi score's sensitivity and specificity equal to 82.2% and 100.0%, respectively [9].

Different pharmacotherapeutic strategies have been assessed to treat NAFLD, but there are currently no established pharmaceutical or nutraceutical therapies and available guidelines only suggest lifestyle changes [10-12]. Clinical trials are being