中文題目：經類核苷酸治療之慢性 B 型肝炎病人，螺旋藻可降低血清 B 型肝炎表面抗原定量濃度–開放式隨機分派對照試驗，期中報告

英文題目：Supplement of Spirulina Reduces Quantitative Hepatitis B Surface Antigen (qHBsAg) in Patients with Chronic Hepatitis B under Nucleos(t)ide Analogues Therapy -
An Open-Label, Randomized Controlled Trial, A Preliminary Report

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Background:

Chronic hepatitis B (CHB) is one of the leading causes of cirrhosis and hepatocellular carcinoma. Serum quantitative hepatitis B surface antigen (qHBsAg) correlates well with covalently closed circular DNA (cccDNA) and total intrahepatic hepatitis B virus (HBV) DNA. It can also predict the immune clearance of cccDNA.

Spirulina platensis, a cyanobacterium used frequently as a dietary supplement, had been found to exhibit many immune-moderating and antiviral activities. However, the therapeutic function of Spirulina on CHB remains unknown.

The aim of this study is to investigate the synergistic effect of Spirulina and nucleos(t)ide analogues on CHB, which has been well-characterized by the serum levels of qHBsAg, the indicator for the immune clearance of cccDNA.

Materials and Methods:

The spirulina species (Taiwan FEM-102 strain) was applied to sixty patients of CHB, who had received nucleos(t)ide analogues for more than one year without detectable serum HBV DNA (<20 IU/mL). The patients were randomized into 3 groups: (1) control group (not received Spirulina), (2) low-dose group (3 g Spirulina daily) and (3) standard-dose group (6 g Spirulina daily).

All patients received a 6-month follow-up period and serum samples were obtained. Steatosis and fibrosis were evaluated by Fibroscan®. At the end of the study, levels of qHBsAg and steatosis / fibrosis were investigated. Rank-sum test was applied to compare the differences among three groups.

This study has been proved and registered at ClinicalTrials.gov with the number of N201608026.

Results:

There was no statistical significant difference in baseline of age, gender, alanine aminotransferase (ALT), HBeAg status and severity of steatosis / fibrosis among three groups. There was a significant decrease of qHBsAg in standard-dose group, compared with low-dose group and control group (-58.57 vs. -14.8 and +28.65; $p < 0.001$). However, there was no significant difference in steatosis / fibrosis among three groups.

Conclusion:

In our preliminary study, the spirulina species (Taiwan FEM-102 strain) could be a promising supplement to patients with CHB under nucleos(t)ide analogues therapy. The mechanism of immune clearance of qHBsAg is worthy to be further investigated.