Clinical Application of Lactoferrin for the Treatment of Chronic Hepatitis C

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Summary
Pilot trials and initial phase 2 dose-response trials of lactoferrin have suggested that lactoferrin administration may decrease the serum level of hepatitis C virus (HCV) RNA in patients with chronic hepatitis C. Therefore, a double-blind randomized controlled trial was undertaken in treatment-naive patients with chronic hepatitis C. Lactoferrin treatment was well tolerated and no serious toxicities were observed; however, there was no significant difference in virologic response rates between the lactoferrin group and the placebo group. Next, we examined whether or not lactoferrin was useful as an adjuvant to interferon/ribavirin therapy in patients with chronic hepatitis C. A prospective randomized trial of interferon/ribavirin plus lactoferrin versus interferon/ribavirin plus placebo was undertaken in treatment-naive patients with chronic hepatitis C. The sustained biochemical response in the lactoferrin group was superior to that in the placebo group; however, there were no significant differences in the primary and sustained virological remissions between the two groups. Although orally administered lactoferrin does not demonstrate any significant virological efficacy in patients with chronic hepatitis C, we are currently conducting a double-blind randomized controlled trial comparing lactoferrin with a placebo to clarify its usefulness as an adjuvant to pegylated interferon/ribavirin therapy in patients with chronic hepatitis C.