

Abstract

Acetaminophen is widely used as a common analgesic agent, but toxic liver injury is a well known side effect of acetaminophen when used long-term. Compared to the clinical doses of acetaminophen used in Western countries and in China, the clinical doses used in Japan have been lower, and the drug potency is not high. The clinical doses of acetaminophen in Japan were increased in 2011, but the incidence of toxic liver injury remains to be investigated. In this study, the pharmacokinetics of acetaminophen were compared between Chinese and Japanese subjects, given that both are Asians and acetaminophen has been prescribed at high doses with an average of approximately 1,000 mg for many years. A single oral dose of acetaminophen 1,000 mg was administered to healthy Japanese and Chinese volunteers (8 participants each), and the pharmacokinetic parameters and urinary excretion rates were measured. No differences in pharmacokinetics of acetaminophen were observed between Japanese and Chinese subjects, and no differences in 24-h urinary excretion rates of unchanged acetaminophen and acetaminophen glucuronide as well as 4-acetaminophen sulfate and 3-cysteinyloxyacetaminophen were found. The pharmacokinetics of acetaminophen were similar in Chinese and Japanese subjects, and the risk of developing drug-induced toxic liver injury associated with an increase in acetaminophen dose is predicted to be comparable in the two ethnic groups.