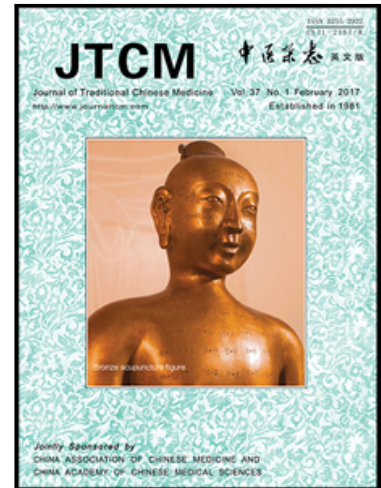


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Potential chronic liver toxicity in rats orally administered an ethanol extract of Huangqin (*Radix Scutellariae Baicalensis*)

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Abstract

OBJECTIVE: To investigate the potential chronic liver toxicity of oral administration of ethanol extract of Huangqin (*Radix Scutellariae Baicalensis*) (SBE) in Wistar rats.

METHODS: SBE was administered to rats by gavage for 26 weeks, at doses of 300, 1250, or 2500 mg \cdot kg⁻¹ \cdot d⁻¹ respectively. The rats were euthanized at the end of 13 and 26 weeks daily oral dosing and following 4 weeks of recovery time. The changes of hematology, urinary, blood biochemistry and histomorphology were examined at each time point and focus on liver function and histological changes.

RESULTS: When SBE at a dose of up to 2500 mg \cdot kg⁻¹ \cdot d⁻¹ was fed to male and female rats for 26 weeks, the liver tissue showed some inflammatory change that predominated by leukocyte infiltration but returned to normal after withdrawal. In addition, high-dose SBE treatment of 26 weeks in rats, glucose, electrolyte and lipid levels also have some changes. In addition, there are no other functional or organic lesions related to SBE treatment.

CONCLUSIONS: Long-term and high-dose SBE may cause liver damage, however, the structural damage of the liver can be restored after the ethanol extract stopping. SBE will be well-tolerated for long-term use as a drug or health food, but in order to ensure drug safety, liver function, and serum glucose, electrolyte and lipid levels should be monitored when using SBE long term.

Keywords: Scutellaria baicalensis; Toxicity tests, chronic; Liver; Administration, oral

INTRODUCTION

Huangqin (*Radix Scutellariae Baicalensis*) is a widely used herb in both Eastern and Western traditional medicine. In China, it has a long medicinal history of 2000 years, and is usually used as the main raw material to prepare traditional herbal formulations and modern Chinese medicines.¹⁻³ Huangqin (*Radix Scutellariae Baicalensis*) has various pharmacological effects and is mainly used in the clinical treatment of respiratory infections, pulmonary heat, enteritis, dysentery, jaundice, purulent infection and gastrointestinal infections.^{4,5} Additionally, it was used as a nerve tonic, sedative and anticonvulsant by Native Americans and Europeans.^{6,7} Recent research has revealed that Huangqin (*Radix Scutellariae Baicalensis*) also possesses potent anticancer, antidiabetic and fat decreasing activities.⁸⁻¹² Based on these beneficial properties, Huangqin (*Radix Scutellariae Baicalensis*) has been used as an ingredient in botanical formulations of health foods which promote health functions such as relieving the inflammatory immune response, combating pathogen and so on.¹³ Its effective components are mostly flavonoids, which decrease inflammation, stop tumor growth, and have antibacterial, antiviral, antiplatelet aggregation, anti spasmogenic and antioxidant properties.¹⁴⁻¹⁷ Dozens of flavonoids compounds have been extracted and identified from Huangqin (*Radix Scutellariae Baicalensis*), including baicalein, wogonin, oroxylin A, baicalin, wogonoside, and oroxylin A-7-glucuronide.^{1,2}

In ICR mice, acute (14-d), subchronic (28-d), and chronic (90-d) safety trials of refined extracts of Huangqin (*Radix Scutellariae Baicalensis*) have been performed and there were no significant differences between the extract treated and placebo groups.¹⁸ Studies confirmed that in rats, dogs, and even human receiving long-term (rats and dogs for up to 26 weeks, human for up to ten days) oral high-doses of the major bioactive Huangqin (*Radix Scutellariae Baicalensis*)-derived flavonoids (including baicalin, baicalein and wogonoside), no drug-related adverse reactions were observed.¹⁹⁻²⁴ Therefore, the main bioactive constituents of Huangqin (*Radix Scutellariae Baicalensis*) were considered safe, well tolerated and without serious accumulation effect. In contrast, hepatotoxicity of the extract of this herb have been reported in the clinic: four patients from the United States who had used Huangqin (*Radix Scutellariae Baicalensis*) in a dietary supplement displayed hepatotoxicity,²⁵⁻²⁸ while nineteen Japanese patients developed liver injury after the use of the herb.²⁹ Thus, whether Huangqin (*Radix Scutellariae Baicalensis*) is hepatotoxic

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