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漢方方剤四逆散の散剤および煎剤の同等性
── 散剤の溶出試験による煎剤との比較 ──

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Equivalence of the Dosage Forms of the Kampo Medicine Shigyaku-san
— Comparison of the Powder and Decoction by Dissolution Testing —

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Abstract

Objective: In several Chinese medicines, different formulations, such as decoctions, ground powders, and pills are prepared from the same variety of herbs. It has been suggested that ground powders and pills have an equivalent effect as decoctions even although the amounts of the prescribed herbs for the powder and pill are lower than in the decoction. Saikosaponin b_2 (SA) and Glycyrrhizin (GL), representative crude drug components of a Chinese medicine prescription, Shigyaku-san, were investigated. In addition, the equivalence of powders and decoctions were compared using dissolution tests.

Methods: Samples of 5.0, 4.0, 2.0 and 1.5 g of Saiko, Syakuyaku, Kizitsu and Kanzou were weighed, respectively, to prepare the prescription, Shigyaku-san. This prescribed Shigyaku-san and 250 mL distilled water were decocted slowly until the total volume was 125 mL, then the content of SA and GL in the decoction were measured. Herbs, of the same lot and weight ratio as the decoction of Shigyaku-san, were also mixed, then ground to obtain powders. SA and GL in the ground powders were extracted by an appropriate solvent, then measured by HPLC. Dissolution tests on the ground powders were carried out using the paddle method described in JP15 using pH1.2, 4.0, and 6.8 buffer solutions or distilled water as a test solution.

Results: The SA content of the ground powders was 5 times higher than that in the decoctions and the GL content of the ground powders was the same as that in the decoctions per daily dose (1.05 times higher in the decoctions), even although their herbs were about half the dose of the decoctions. As a result of the dissolution test, the amounts of dissolved SA and GL were increased on reducing and increasing the pH of the test solutions, respectively. A rate-limiting step of dissolution was observed in the SA dissolution test at pH1.2 and using 900 mL test solution. It may be that the gastrointestinal absorption of SA depends on the volume and/or pH of the gastrointestinal tract. The rate of GL dissolution was so fast that almost all the GL in the ground powders had dissolved within 30 minutes.

Conclusion: These results suggest that ground powders of Chinese medicines have an equivalent medicinal effect as decoctions because the contents of the representative crude drug components in ground powders are not less than in decoctions, even although the amounts of herbs used for the prescription of ground powders were less than for the decoctions.

Key words: Dosage form equivalency, Decoction, Powders, Shigyaku-san, Saikosaponin b_2, Glycyrrhizin, Dissolution test