

〔一般論文〕

Comparative Clinical Evaluation of Efficiency and Safety between Original Drug and Generic Products (I)

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Summary : Annual healthcare costs in Japan are currently increasing. Therefore, the Japanese government is recommending the use of generic products. However, some reports have suggested a decrease in drug efficacy and the development of adverse effects when exchanging the original drug with a generic product. The purpose of this study is the comparison of clinical efficiency between original drugs and generic products. Candidate drugs were 2 types of angiotensin-converting enzyme inhibitor, enalapril and lisinopril, as it is important to reduce health expenditure for hypertension. We retrospectively evaluated the efficiency (blood pressure and heart rate), safety (biochemical parameters), medication adherence based on patient data. We set the follow-up period at 6 months before and after substitution. Data were analyzed by Paired-Sample t-tests (statistical significance level of 0.05). A total of 27 patients in the enalapril study and 35 patients in the lisinopril study became candidates for the present study. We found that there were no significant differences before and after substitution. Although there were differences in some biochemical parameters, the range remained within normal levels. With regard to medication adherence, we found no significant differences.

Key words : generic product, efficiency, safety, angiotensin-converting enzyme inhibitor

Background

In recent years, healthcare costs in Japan have steadily increased. In 2008, they exceeded 33 trillion yen, including 6.6 trillion yen (20% of the total healthcare costs) in drug costs. The Japanese government has thus attempted to reduce the costs

associated with drugs, and one of the approaches to achieve this has been to recommend generic products. Although the range of generic products on the Japanese National Health Insurance price list has increased, they represent only 16.8% of the market share. This percentage is lower than the United States or Europe, where shares are about 40-60%. To promote generic products using in Japan, we have to cast aside apprehension among health professions who use them. In fact, there are some report

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