〔一 般 論 文〕

先発医薬品と後発医薬品における添加剤の相違に関する研究

A Study on the Differences in Additives between Brand-name and Generic Drugs

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Summary：The apprehension toward generic drugs may be due in part to a perception of differences in additives between brand-name and generic drugs. In this study, we conducted an analysis of additives that may induce adverse reactions such as allergies or aspirin-induced asthma. Using information provided in package inserts, we examined the use of the target additives in orally administered drugs, topical drugs, and injectable drugs, and compared the differences in additive use between brand-name and generic drugs. In addition, we also compared the additive content between brand-name and generic injectable drugs, and investigated the relationship between additive content and warning statements.
The results showed that for all target additives, there were no statistical differences in the frequencies of additive use between brand-name drugs and generic drugs, regardless of the administration route. However, the analysis revealed that there were certain additives that were more frequently used in either generic drugs or brand-name drugs. Furthermore, there were no major differences detected in additive content, indicating the need for cautious utilization of both brand-name drugs and generic drugs based on factors such as patient history of adverse drug reactions and food allergies.
The lack of consistent findings with regard to the association between additive content and warning statements suggests that, as exemplified by the European system, Japan should consider the necessity of developing scientifically based guidelines for warning statements concerning drug additives.

Key words：additives, generic drugs, drug allergy, side effects

要旨：後発医薬品を不安視する理由の一つとして，後発医薬品が先発医薬品と異なる添加剤を使用しているとの指摘がある．そこで，本研究では，アレルギーやアスピリン喘息の原因となる可能性のある添加剤を対象とし，添付文書情報を利用して，内用剤，外用剤，注射剤それぞれにおける対象添加剤の使用状況を調査し，先発医薬品と後発医薬品の添加剤の相違を比較した．さらに，注射剤での先発医薬品と後発医薬品の添加剤含有量の比較及び添加剤含有量と注意喚起表示の関係についても調査した．
その結果，対象添加剤全体では，いずれの剤型でも先発医薬品と後発医薬品の対象添加剤の使用頻度に統計学的有意差は認められなかったが，一部に後発医薬品での使用頻度が高い添加剤，及び先発医薬品での使用頻度が高い添加剤が認められた．また，添加剤含有量には大きな違いは認められず，先発医薬品，後発医薬品かにかかわらず，患者のアレルギー歴等を踏まえた注意が必要と考えられた．
添加剤含有量と注意喚起表示の有無に関しては一貫性が認められず，日本においても，欧州の制度を参考に，添加剤の注意喚起表示に関し科学的根拠に基づくガイドライン等の必要性を検討すべきと考えられた．

キーワード：添加剤，後発医薬品，アレルギー，副作用

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