

●原著

ジェネリック医薬品の医薬品情報と薬価を観点とした価値評価

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Evaluating the Merits of Generic Drugs from the Standpoint of Drug Information and NHI Drug Price

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(Received November 17, 2001)
(Accepted March 22, 2002)

Abstract :

Objective—The merits of pharmaceuticals are determined by their effectiveness, safety, quality, and other factors, including the completeness of drug information. To study the comparative merits of forerunner drugs and their later-developed generic equivalents, we conducted an assessment from the standpoint of drug information and NHI (National Health Insurance) drug price data.

Design—Internal medicines for which emergency safety information has been distributed within the past 3 years were evaluated in terms of drug information and NHI drug price data.

Method—Scores were assigned to drug information in package inserts, interview forms, and emergency safety information publications to assess the merits of forerunner drugs and corresponding “me-too drugs.”

Results—Scores revealed a tendency for information on generic drugs to be less available than that for forerunner drugs. For diclofenac sodium, scores for generics averaged 19.5 ± 16.9 points (Mean \pm SD) compared to 83.5 for original brand-name products. The average score for generic ticlopidine hydrochloride was 19.6 ± 7.8 points (Mean \pm SD), compared to 96.0 for the brand-name forerunner, and the average score for generic benzbromarone was 16.6 ± 11.4 points (Mean \pm SD), compared to 52.0 points for the forerunner product.

Conclusion—A great disparity exists between information provided for forerunner drugs and that for generics, and this has a major impact on the relative merits of generic drug products. Problems arise in the actual use of generic drugs because information on these pharmaceuticals is insufficient. However, new overall evaluation criteria will be needed in future evaluations of comparative merits.

Keyword : drug information, generic drugs, drug evaluation, drug price