Jpn. J. Drug Inform., 8 (2): 121～127 (2006).

カルシウム拮抗薬 Nifedipine 徐放錠の医薬品添付文書における薬物動態情報に関する研究
── 先発医薬品と後発医薬品の比較 ──

本間雅士*、平山武司、高橋賢成、黒山政一

北里大学東病院・薬剤部　〒228-8520　神奈川県相模原市麻溝台 2-1-1

Study on the Pharmacokinetic Information Provided in Package Inserts of Generic Sustained release products Containing Nifedipine, Carcium antagonist

Masashi Homma, Takeshi Hirayama, Masaaki Takahashi, Masakazu Kuroyama

Department of Pharmacy, Kitasato University East Hospital　2-1-1 Asamizodai, Sagamihara, Kanagawa, 228-8520 Japan

(Recevied April 5, 2006
Accepted June 12, 2006)

Abstract

Objective: We have studied the pharmacokinetic information provided in package inserts of sustained release products containing nifedipine, a calcium antagonist.

Design: We examined a total of 23 products, 1 original and 22 generic products.The pharmacokinetic parameters (Cmax, tmax, $t_{1/2}$, AUC) documented in the package inserts of the products are used in the calculation.　The ratio of the parameters of the original product (Op) to those of the generic product (Gp) is expressed as follows: Pharmacokinetic parameter ratio (PPr) = Gp/Op

Results: The following are the results of PPr for the generic products with pharmacokinetic information listed in the package inserts : Cmax, 1.16 ±0.23, 0.93-1.53 (mean ±S.D., min-max) ; tmax, 1.12±0.18, 0.86-1.42 ; $t_{1/2}$, 1.39±0.43, 0.94-2.08 ; AUC, 1.19±0.59, 0.77-1.61.

Conclusion: Although the equivalence between the original and generic products had already been established, we have found that there are a number of deviations from the acceptable range for bioequivalence, 0.8-1.25, and the result indicates that some of the information on the generic products may cause confusion or misunderstanding.

In conclusion, the package inserts of the generic products should include the name of the brand-name product used in the bioequivalence study, the name of the manufacturing company, and the obtained parameters of the brand-name and generic products.　We believe if the above information is documented, it will make the package inserts more useful, helping physicians choose and use sustained release products containing nifedipine.

Key word: calcium antagonist, nifedipine, pharmacokinetic imformation, generic products, bioequivalence