

Pharmacokinetics of nifedipine in Taiwanese

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Abstract

To elucidate the pharmacokinetics of nifedipine in Taiwanese, a retrospective review of nifedipine bioequivalence studies completed in Taiwan in the past 5 years was conducted. A total of 198 healthy male volunteers were given a single dose of a 10 mg Adalat® capsule as a reference drug after overnight fasting. Pharmacokinetic parameters derived from Adalat® administration were calculated by non-compartmental analysis with the WinNonlin program. After oral administration of an immediate-release dosage form of a 10 mg nifedipine capsule to Taiwan residents, a skewed distribution with no clear evidence of bimodality of pharmacokinetic parameters was observed. The mean C_{max} was 143.12 ± 53.48 ng/ml, the mean AUC was 293.77 ± 115.62 ng.h/ml, the mean T_{1/2} was 3.08 ± 1.61 h, and the median value of T_{max} was 0.61 h. Compared with other published studies, the C_{max} and AUC of nifedipine after 10 mg administration were significantly higher in Taiwanese than in British and American subjects. However, the C_{max} and AUC were similar to those of Indian and Mexican subjects. According to the antimode of AUC distribution of 22.5 ng.h/ml/mg proposed by Kleinbloesem, 69.7% of Taiwanese can be categorized as slow metabolizers. Based on the results in this study, the majority of Taiwanese show lower activity of nifedipine metabolism.