Ketoprofen 첩포제의 경피적용에 따른 혈장농도 및 피부자극의 검토

서울의대 약리학교실 · 서울대학교병원 임상약리실 : 임동석 · 장인진 · 신상구
서울의대 피부과학교실 : 유재학 · 은희철

Background : The aim of this study was to determine the relative bioavailability and the degree of skin irritation of new matrix type ketoprofen transdermal system (Ketotop®) by comparing with different formulation(M) having the same dose strength marketed.

Method : Three transdermal patches of 30mg ketoprofen and one control surgical plaster were applied for 24 hours to 12 male volunteers in a balanced, randomized crossover design. Blood samples were collected serially upto 28 hours and plasma concentrations of ketoprofen were analysed by HPLC method. Clinical scoring, transepidermal water loss and laser doppler flowmetry were used for the evaluation of the irritation of the tested formulations.

Results : The new matrix formulation(Ketotop®) showed significantly higher plasma ketoprofen levels from 3 hours after application. Ketoprfen level maintained higher than formulation M by 30mg/ml/patch from 6 hours upto 24 hours in subjects with application of the new matrix type formulations. The AUC and Cmax of the new matrix type formulation were more than 3 times greater than those of M. Neither of the two trsansdertmal formulations caused any significant skin irritation examined by visual, evapori-metric and laser doppler analysis.

Conclusion : These results suggest that the newly developed matrix type trandermal patch of ketoprofen would show excellent skin permeation relevant to efficacy on local application for the corresponding clinical indications.