

## Abstract

Methylprednisolone is a memberane of synthetic glucocorticosteroid. It is well absorbed from the gastrointestinal tract; metabolism is primarily in the liver and excretion is via the kidney. In this study, two commercial methylprednisolone tablets, Medrol<sup>®</sup> and Menisone<sup>®</sup>, were compared in twelve normal, healthy Taiwanese male volunteers participated in a single-dose, two-period, two-sequence, two-treatment crossover study.

Methylprednisolone plasma concentrations were analyzed with a validated high performance liquid chromatographic method. It was performed on a RP-18e column using a mobile phase of 61% water (pH4.28, by glacial acetic acid), 39% acetonitrile with ultraviolet dection (244nm). This method uses triamcinolone as the internal standard for the determination.

After oral administration of Methylprednisolone 5×4 mg/tablet in the healthyl volunteers, the peak serum concentration of 0.144 µg/ml were achieved about 1.67hrs, the mean area under the serum concentration-time curve ( $AUC_{0-}$ ) was  $0.582\pm 0.096$  µg·hr/ml, the mean terminatial half-life was  $2.709\pm 0.553$  hrs.

There are no significant statistic different between pharmacokinetic parameter ( $p > 0.05$ ) of the two different products, including the peak serum concentration ( $C_{max}$ ), time to peak level ( $T_{max}$ ) and area under the curve (AUC). Base on the result obtained in this study, bioequivalence between these two different products was demonstrated.

## 中文摘要

Methylprednisolone 是一種合成的甾皮質類固醇，具有很強的抗發炎活性。口服後，可由腸胃道快速吸收，在肝臟代謝，經由腎臟排除。本實驗為比較兩種不同處方的 Methylprednisolone 錠劑，Medrol<sup>®</sup> (Upjohn)及 Menisone<sup>®</sup>(培力)，在 12 位健康的志願受試者之生體可用率。

本實驗分析採高效液相層析法分析血漿檢品。以 LiChroCART RP-18 管柱及氘甲烷、醋酸水溶液(氘甲烷：醋酸水溶液=39：61(v/v))為移動相，在 244nm 的紫外光偵測波長下，以 1ml/min 的流速下進行分析。以 Triamcinolone 作為內部標準品。

健康受試者口服給藥 20mg (5×4mg/tablet)後，大約 1.67 小時可達最高血中濃度 0.144  $\mu$ g/ml；平均曲線下面積(AUC<sub>0-</sub>)約為 0.582±0.096  $\mu$ g·hr/ml 而排除半衰期則約為 2.709±0.553 hrs。

本實驗結果以統計學方法 two-way ANOVA 比較此兩種不同處方產品的動力學參數，包括了 C<sub>max</sub>、T<sub>max</sub>、AUC<sub>0-12</sub>及 AUC<sub>0-</sub>。計算結果發現並無統計學上顯著的差異。因此可認為 Medrol<sup>®</sup> tablets 及 Menisone<sup>®</sup> tablet(培力)此兩種不同產品是具有生體相等性的