

论著

## 甘氨双唑钠的 I 期临床药代动力学

付良青\*, 黄丰, 郭军华, 高洪志, 梁月琴, 李杰, 吴德政

(军事医学科学院附属医院临床药理科, 北京 100850)

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**摘要** 目的 对一类新药肿瘤放射增敏剂甘氨双唑钠(CMNa)进行单剂量和多剂量 I 期临床药代动力学研究, 对其吸收、分布、代谢、排泄及CMNa在体内的蓄积性作一评价。方法 6个单剂量组有24名肿瘤病人, 5名肿瘤病人受试者参与多剂量研究; 采用高效液相-二极管阵列色谱法测定肿瘤放疗增敏剂CMNa及其代谢产物甲硝唑的血药浓度和尿药浓度, 用3P97软件对各单剂量组和多剂量组的血药浓度-时间曲线拟合, 并计算药代动力学参数。结果 6个单剂量组和多剂量组的CMNa血药浓度时间曲线经拟合均符合开放型二室模型, 400, 500, 600, 700, 800和900 mg $\cdot$ m<sup>-2</sup>组的主要药代动力学参数  $t_{1/2\beta}$  为0.76~2.62 h,  $c_{\max}$  为13.31~43.90 mg $\cdot$ L<sup>-1</sup>, AUC为8.68~29.94 mg $\cdot$ h $\cdot$ L<sup>-1</sup>, 且单剂量组的  $c_{\max}$  及AUC与剂量成正比。700 mg $\cdot$ m<sup>-2</sup>单次给药和连续9次给药的多剂量组的肿瘤病人血药浓度-时间曲线几乎相吻合, 各药代动力学参数值和排泄率没有统计学差异。结论 CMNa在肿瘤病人体内分布和消除均很快, 一定间隔服用不会在病人体内蓄积, 是一个较安全的放射增敏药物。

**关键词** [甘氨双唑钠](#) [药代动力学](#) [色谱法](#), [高压液相](#) [放射疗法](#)

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## Phase I clinical pharmacokinetics of glycididazolium natrium

FU Liang-Qing\*, HUANG Feng, GUO Jun-Hua, GAO Hong-Zhi, LIANG Yue-Qin, LI Jie, WU De-Zheng

(Department of Clinical Pharmacology, Affiliated Hospital, Academy of Military Medical Sciences, Beijing 100850, China)

### Abstract

**AIM** To study the pharmacokinetics of a new radiosensitizing agent glycididazolium natrium (CMNa) in lung cancer patients after single- and multiple dose administration. **METHODS** Twenty-four cancer patients were for single-dose study; and 5 patients were for multiple-dose study. The CMNa and metronidazole concentrations in blood and urine were determined by HPLC with UV detector. The blood CMNa concentration-time curves were simulated by 3P97 software and the pharmacokinetic parameters were calculated. **RESULTS** The blood CMNa concentration-time curves in single-dose groups were fitted to two-compartment open model,  $t_{1/2\beta}$  were 0.76-2.62 h,  $c_{\max}$  were 13.31-43.90 mg $\cdot$ L<sup>-1</sup>. AUC were 8.68-29.94 mg $\cdot$ h $\cdot$ L<sup>-1</sup> in 400, 500, 600, 700, 800 and 900 mg $\cdot$ m<sup>-2</sup> dose groups, respectively and their  $c_{\max}$  and AUC were direct proportional to doses. The blood concentration time curves, pharmacokinetics parameters, and excretion ratios between single-dose and multiple-dose were similar, and there was no significant difference. **CONCLUSION** CMNa distributed and eliminated rapidly, so CMNa will not accumulate in patients' bodies if it is administered at an appropriate interval.

**Key words** [glycididazolium natrium](#) [pharmacokinetics](#) [chromatography](#) [high pressure liquid radiotherapy](#)

DOI:

通讯作者 付良青 [fuliangqing@yahoo.com](mailto:fuliangqing@yahoo.com)

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