Tumori, 95: 691-696, 2009

Thalidomide improves prevention of chemotherapy-induced gastrointestinal side effects following a modified FOLFOX7 regimen: results of a prospective randomized crossover study

Yunpeng Liu, Jingdong Zhang, Yuee Teng, Lingyun Zhang, Ping Yu, Bo Jin, Mingfang Zhao, Jing Shi, Shizhou Liu, Na Song, and Zhi Li

Department of Medical Oncology, the First Hospital, China Medical University, Shenyang City, China

ABSTRACT

Aims and background. Thalidomide was firstly evaluated for the control of chemotherapy-induced gastrointestinal side effects following a modified FOLFOX7 (mFOLFOX7) regimen.

Methods and study design. Chemotherapy-naive patients with malignant tumors were randomized into two groups: A-B group (A, 0.3 mg of ramosetron plus 10 mg of dexamethasone on day 1, was given intravenously in the first cycle, and B, 0.3 mg of ramosetron plus 10 mg of dexamethasone on day 1 intravenously plus 150 mg orally twice daily of thalidomide on days 2 through 5, in the second cycle) and B-A group (those drugs were given in the reverse sequence). The primary end point was the efficacy of thalidomide in controlling delayed (days 2 through 5) chemotherapy-induced nausea and vomiting (CINV). The secondary end point was the safety of thalidomide.

Results. Of 52 patients enrolled, 50 patients (96%) were assessable. Complete response rates of delayed nausea (no nausea) were higher with group B than group A (52% *vs* 24%, $P = 0.004$ on day 2; 58% *vs* 24%, $P = 0.001$ on day 3; and 60% *vs* 36%, $P = 0.016$ on day 4). Complete response rates of delayed emesis (no emetic episodes, no rescue therapy) for group B and A also showed significance (86% *vs* 66%, $P = 0.019$ on day 2 and 76% *vs* 56%, $P = 0.035$ on day 3). Complete response rates on anorexia for group B were higher than those for group A on days 2 through 5. More patients in group B reported sedation or dizziness than in group A (42% *vs* 9.6%; $P = 0.000$).

Conclusions. Thalidomide improves prevention of chemotherapy-induced gastrointestinal side effects following the mFOLFOX7 regimen. It is a safe, effective antiemetic.

Key words: chemotherapy-induced nausea and vomiting (CINV), ramosetron, thalidomide.

Acknowledgments: We thank Dr Xiujuan Qu (Medical Oncology Department, the First Hospital, China Medical University) and Dr Hongyuan Liang (Interventional Department, the Shengjing Hospital, China Medical University) for their helpful advice for completion of the article.

Correspondence to: Professor Yunpeng Liu, Department of Medical Oncology, the First Hospital, China Medical University, NO.155, North Nanjing Street, Heping District, 110001, Shenyang City, China.
Tel +86-24-81018401;
fax +86-24-83282543;
e-mail liuyunpeng@medmail.com.cn;
cmuliuyunpeng@yahoo.cn

Received June 3, 2008;
accepted May 5, 2009.