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.