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A randomized open-label parallel-group study comparing ondansetron with ondansetron plus dexamethasone in patients with metastatic breast cancer receiving high-dose epirubicin. A Hellenic Cooperative Oncology Group study.

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Source

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Abstract

AIMS AND BACKGROUND:

The purpose of this multicenter randomized, open-label, parallel-group study was to assess whether the addition of low-dose dexamethasone to ondansetron results in improved control of chemotherapy-induced emesis in patients undergoing first-line chemotherapy with high-dose epirubicin.

METHODS & STUDY DESIGN:

Patients were randomized to receive either 24 mg of ondansetron or 24 mg of ondansetron plus 8 mg of dexamethasone administered as an intravenous infusion 30 minutes prior to administration of chemotherapy. Both groups of patients received 8 mg of ondansetron given orally from day 2 to 5 two times daily. Fifty-three patients received ondansetron and 50 received ondansetron plus dexamethasone. The patients recorded nausea and the number of vomits and retches daily on diary cards.

RESULTS:

Significantly more patients in the ondansetron plus dexamethasone group experienced neither vomiting nor retching during the first day of the first course of chemotherapy compared to those receiving ondansetron alone (79.6% vs 53.8%, P = 0.0062). Furthermore, there was a trend in favor of ondansetron plus dexamethasone in the control of nausea. There was no statistically significant difference between ondansetron plus dexamethasone versus ondansetron alone in protecting patients from emesis between days 2 and 5 of the first course of chemotherapy (66.7% vs 62.7%, P = 0.68). This was probably due to the small sample size. Ondansetron was well tolerated, with 15 patients (15%) reporting adverse events such as headache or constipation.

CONCLUSIONS:

It appears that ondansetron given intravenously in combination with dexamethasone is more effective than ondansetron alone in the control of acute emesis in patients undergoing their first course of chemotherapy with high-dose epirubicin. No difference between the regimens was found with regard to nausea and delayed emesis control.