Omeprazole: outcome benefit for patients treated for bleeding peptic ulcers?

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Comments

In this study, patients with acutely bleeding peptic ulcers and a high risk of recurrent bleeding, who received early treatment with high dose intravenous omeprazole, showed a significant outcome benefit compared to a placebo group. By implication, the success of this intervention can be attributed to effective acid suppression in the first 72 h post endoscopy. However, the placebo group were denied any form of acid suppression during this period. This goes against standard clinical practice in which either oral treatment is started or intravenous H2 blockade administered. Thus, although the outcome benefit is clearly demonstratred, the comparison with a placebo group rather than one who received the current standard of care seriously diminishes the impact of the result.

Introduction

Endoscopic therapy is a highly effective treatment for bleeding peptic ulcer disease. However, recurrent bleeding occurs in 15% to 20% patients and carries a high morbidity. Acid suppression has been shown to enhance ulcer healing and improve intra-lesional platelet aggregation. Previous outcome studies of early acid suppression have given conflicting results, though a statistically insignificant trend towards improved outcomes in patients treated with proton pump inhibitors has been noted.

Methods

- Patients with a high risk of recurrent bleeding (active bleeding or a visible vessel at the time of endoscopy) who had undergone a successful endoscopy procedure (epinephrine injection +/or thermocoagulation) were eligible for study entry. Patients in whom bleeding was not initially controlled by endoscopy underwent surgical treatment and were excluded

- After endoscopy, patients were randomized in a double blind fashion to receive either an intravenous infusion of placebo or omeprazole (80 mg bolus injection followed by a continuous infusion of 8 mg/h for a period of 72 h). After the infusion both groups received oral omeprazole 20 mg/day for 8 weeks, and treatment for *Helicobacter pylori*colonisation if indicated

- The primary end-point was recurrent bleeding within 30 days (data assessed by intention-to-treat analysis)

Results

A total of 120 patients were enrolled in each group. Two patients in the treatment group and four in the placebo group were lost to follow up. Bleeding recurred within 30 days after treatment in eight patients (6.7%) in the omeprazole group, as compared with 27 (22.5%) in the placebo group (odds ratio, 3.9; 95% confidence interval, 1.7 to 9.0). Five patients (4.2%) in the omeprazole group died within 30 days after endoscopy, as compared with 12 (10%) in the placebo group ($P = 0.13$). None of the five deaths in the omeprazole group was caused by recurrent bleeding. There was a statistically significant reduction in transfusion requirements ($P = 0.03$) and hospital stay ($P= 0.006$) in the treatment group.

References

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