Tranexamic acid in addition to conventional management was not superior to conventional treatment alone in a prospective randomized trial of upper gastrointestinal bleeding

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Introduction: Bleeding from the gastrointestinal tract (GI) is the most common cause of hospitalization for gastrointestinal disease. One of the key risk factors for mortality is rebleeding after initial hemostasis. Tranexamic acid is an antifibrinolytic agent with a proved safety profile that has been demonstrated to improve survival in patients with multitrauma and major bleeding. Thus tranexamic acid may improve outcomes in upper GI bleeding. Methods: Prospective randomized study of tranexamic acid in addition to conventional treatment vs. conventional treatment alone for patients with upper GI bleeding. Tranexamic acid was administered intravenously as 1 gr boluses every 6 hours for the first 72 hours and orally 2 gr tid for 7 additional days. Results: A preset analysis was performed after 20 patients were recruited; nine were in the control group. Mean age was 56.4 (SE 4.3), 78% were males, mean hemoglobin at presentation was 9.7 (SE 0.73) mg/dL. High risk stigmata were found in 42%. There were no significant differences in baseline characteristics or endoscopic findings between groups. Two cases of rebleeding (10.5%) occurred during the index hospitalization and an additional one within 180 days, all in the treatment arm (p = 0.2). There were no mortalities. Secondary did not differ between groups. No side effects secondary to tranexamic acid were detected. Conclusions: The addition of tranexamic acid to conventional management in upper GI bleeding was not superior to conventional treatment alone in this small randomized prospective study. All events occurred in the treatment group suggestive of possible harm.