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Abstract: BACKGROUND: Inappropriate activation of hemostasis and inflammation may contribute to postoperative morbidity and mortality. The serine protease inhibitor, aprotinin, has been shown to prevent tissue and organ injury in laboratory and animal studies. In this retrospective analysis, we evaluated the relationship of aprotinin therapy with organ dysfunction in humans undergoing coronary artery bypass graft surgery (CABG). METHODS: Data from prospective randomized, double-blind, placebo-controlled studies evaluating the safety and efficacy of full-dose aprotinin (2 million KIU load, 2 million KIU pump prime, and 0.5 million KIU/h continuous infusion) to reduce blood loss and transfusion requirements in patients undergo CABG (placebo, n = 861; aprotinin, n = 862) were examined retrospectively. Primary end-points were death, adverse cerebrovascular outcome, myocardial infarction (MI), and pharmacological interventions (inotropic drugs, vasopressors, and antiarrhythmics). RESULTS: Univariate analysis showed that relative to placebo, full-dose aprotinin therapy was associated with significant effects on the incidence of adverse cerebrovascular outcome (odds ratio [OR] 0.42, 95% confidence interval [CI] 0.19-0.93; P = 0.03) and use of inotropic drugs (OR 0.79, 95% CI 0.65-0.97; P = 0.02), vasopressors
(OR 0.74, 95% CI 0.61-0.90; P< 0.01), and antiarrhythmics (OR 0.79, 95% CI 0.65-0.96; P = 0.02), but not death (OR = 1.00, 95% CI 0.54-1.85; P = 1.0) or MI (OR 0.92, 95% CI 0.64-1.31; P = 0.6). Multivariate analysis confirmed results of univariate analysis. CONCLUSIONS: This retrospective analysis of data collected from prospective, randomized, placebo-controlled studies in CABG shows that full-dose aprotinin use was associated with a lower risk of adverse cerebrovascular outcomes and a reduced need for use of vasoactive drugs; the risk of death and perioperative MI was not affected by aprotinin therapy.