Effect of reversal of neuromuscular blockade with sugammadex versus usual care on bleeding risk in a randomized study of surgical patients.

Abstract:

Previous studies show a prolongation of activated partial thromboplastin time and prothrombin time in healthy volunteers after treatment with sugammadex. The authors investigated the effect of sugammadex on postsurgical bleeding and coagulation variables. This randomized, double-blind trial enrolled patients receiving thromboprophylaxis and undergoing hip or knee joint replacement or hip fracture surgery. Patients received sugammadex 4 mg/kg or usual care (neostigmine or spontaneous recovery) for reversal of rocuronium- or vecuronium-induced neuromuscular blockade. The Cochran-Mantel-Haenszel method, stratified by thromboprophylaxis and renal status, was used to estimate relative risk and 95% confidence interval (CI) of bleeding events with sugammadex versus usual care. Safety was further evaluated by prespecified endpoints and adverse event reporting. Of 1,198 patients randomized, 1,184 were treated (sugammadex n = 596, usual care n = 588). Bleeding events within 24 h (classified by an independent, blinded Adjudication Committee) were reported in 17 (2.9%) sugammadex and 24 (4.1%) usual care patients (relative risk [95% CI], 0.70 [0.38 to 1.29]). Compared with usual care,
increases of 5.5% in activated partial thromboplastin time (P< 0.001) and 3.0% in prothrombin time (P< 0.001) from baseline with sugammadex occurred 10 min after administration and resolved within 60 min. There were no significant differences between sugammadex and usual care for other blood loss measures (transfusion, 24-h drain volume, drop in hemoglobin, and anemia), or risk of venous thromboembolism, and no cases of anaphylaxis. Sugammadex produced limited, transient (<1 h) increases in activated partial thromboplastin time and prothrombin time but was not associated with increased risk of bleeding versus usual care.