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Titel des Beitrags: Safety and efficacy of sugammadex for the reversal of rocuronium-induced neuromuscular blockade in cardiac patients undergoing noncardiac surgery.

Abstract: BACKGROUND AND OBJECTIVE: The present randomized, safety-assessor blinded, placebo-controlled trial was designed to assess safety and efficacy of sugammadex, a novel selective relaxant-binding agent, in patients with underlying cardiovascular disease undergoing noncardiac surgery. METHODS: Overall, 116 patients (New York Heart Association class II-III) were randomized and received sugammadex 2.0 mg kg (n = 38), sugammadex 4.0 mg kg (n = 38) or placebo (n = 40) for reversal of rocuronium-induced neuromuscular blockade at reappearance of T2. Safety variables included heart rate, blood pressure and electrocardiogram characteristics, including rate-corrected QT (QTc Fridericia and QTc Bazett) interval. Efficacy was evaluated as time to recovery of the T4/T1 ratio to 0.9 after administration of sugammadex or placebo. RESULTS: There were no significant differences between groups in terms of QTc (Fridericia) interval. Three serious adverse events, one in each treatment group, considered to be possibly drug-related according to the investigator, were cases of mild QTc (Bazett) interval prolongation. Blood pressure and heart rate decreased after initiation of anaesthesia and remained stable in all groups up to 10 min after administration of study drug. Blood pressure was significantly higher (P< 0.05) in both sugammadex
dose groups compared with placebo at 30 min. The decrease in heart rate from baseline (prestudy drug) was significantly greater in the 2.0 mg kg sugammadex group at 2 and 5 min, and, for both sugammadex groups, the increase at 30 min was greater compared with placebo. Both sugammadex doses resulted in considerably shorter time to recovery of the T4/T1 ratio to 0.9 compared with placebo. CONCLUSION: The findings indicate sugammadex 2.0 and 4.0 mg kg can be given safely and effectively for the reversal of rocuronium-induced neuromuscular blockade in patients with cardiovascular disease undergoing noncardiac surgery.