Post-operative alertness and recovery. Sugammadex versus neostigmine/glycopyrrolate and placebo.

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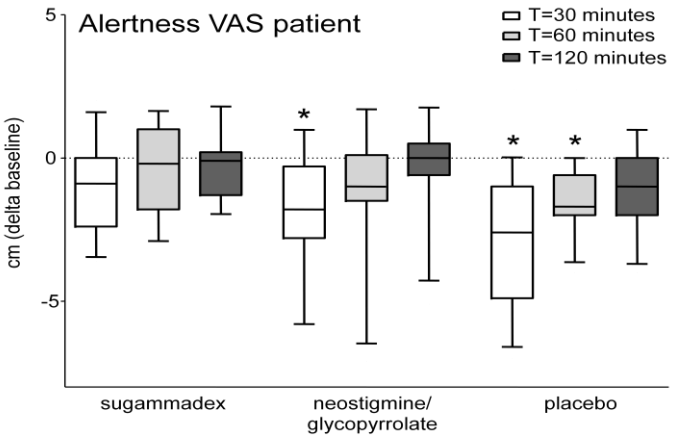
Introduction. Successful ambulatory surgery requires anesthetic and analgesic drugs with a rapid onset and short and reliable duration of action. During the intermediate recovery phase patients should have regained sufficient cognitive and physical competence and be able to return home in the company of a responsible person. We clinically observed that patients seem to be more alert in the early phase of recovery after reversal of neuromuscular blockade (NMB) with sugammadex compared to reversal with a cholinesterase inhibitor or spontaneous recovery. Our primary objective was to assess whether sugammadex has a positive effect on the post operative alertness of the patients.

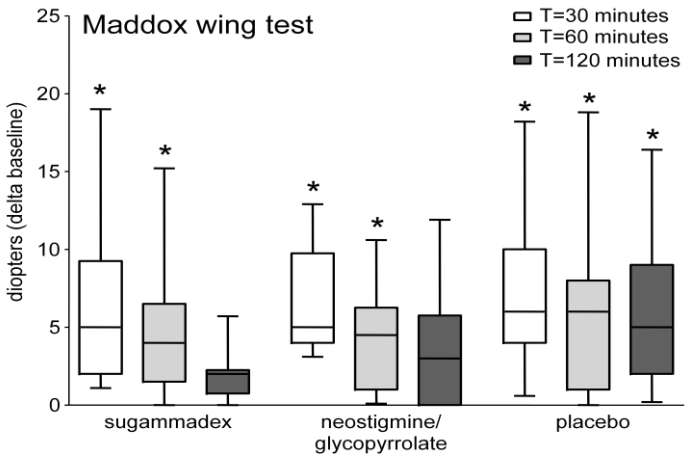
Material and methods. Randomized, controlled observer-blind single centre phase IV study. Patients aged 18-65 years old, ASA I–II undergoing surgical and gynecological shorter than 75 minutes procedures were enrolled. Patients were randomized to receive sugammadex, neostigmine/glycopyrrolate or placebo. Anesthesia was managed with propofol, remifentanil and rocuronium. At the end of the surgery when TOF ratio was ~0,9 the study medication was administered. Cognitive and psychomotor tests (Trail making test and Maddox wing test), Aldrete score, PADSS and visual analogue scale (VAS) were performed 30, 60 and 120 minutes after the surgery.

Results. 33 patients were included. At demographic, intraoperative and baseline were no significant differences between the groups. In the Maddox Wing test, at the last measured time point (120 minutes), the scores of patients in the sugammadex and neostigmine/glycopyrrolate groups were similar to those recorded preoperatively. However, in the placebo group patients still scored significantly worse than preoperatively. Patient's alertness VAS scores in the sugammadex group were similar to preoperative scores during the first test performance and stayed similar to it at *all* postoperative time points. In the neostigmine/ glycopyrrolate group, recovery was slower, with scores reaching levels comparable with preoperatively levels at 60 minutes postoperative. While in the placebo group, VAS scores returned to levels comparable with baseline only 120 minutes postoperative. There were no differences between groups in the Trail making test A, observer's alertness VAS, Modified Aldrete score and PADSS measurements.

Discussion. We report a group of tests to assess patient's recovery and the influence of sugammadex or neostigmine/glycopyrrolate in the phases I and II of recovery. Our main findings were that reversal of NMB resulted in a faster return to the preoperative status in the Maddox wing test, compared with the placebo group. Even though in all groups the TOF ratio was 0.9 at the end of the surgery. Patients reported to be more alert in the VAS in sugammadex group compared with the neostigmine/glycopyrrolate and placebo group. The afferentation theory could explain our findings. This hypothesis predicts that muscle afferent activity is enhanced by antagonizing the neuromuscular block resulting in a sustain cerebral arousal response. Previous intra-operative studies had showed the influence of the neuromuscular blockade antagonism in the depth of anesthesia. We studied patient's recovery after anesthesia using recovery scales, cognitive and psychomotorisch tests showing the recovery's benefit of NMB reversal. These possible benefits can enhance recovery quality not only in recovery phase I but also facilitates the street fitness of the patients, leading to an earlier discharge of ambulatory patients.



Alertness VAS patient. Whiskers indicate 10-90 percentile.* indicates $p<0.05$ vs. preoperative (Friedman test with Dunn's post-hoc test).



Maddox wing test. Whiskers indicate 10-90 percentile.* indicates $p<0.05$ vs. preoperative (Friedman test with Dunn's post-hoc test).

Summary

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Clinical observations presume patients to be more alert in early recovery phases after neuromuscular block reversal with sugammadex compared to cholinesterase inhibitor or spontaneous recovery. Our objective was to assess if sugammadex had a positive effect on postoperative alertness. 33 patients were included in this randomized controlled observer-blinded study. At the end of the surgery when TOF ratio was 0,9 patients received sugammadex, neostigmine/glycopyrrolate or placebo. Recovery scores, cognitive en psychomotor tests were performed 30, 60 and 120 minutes postoperative. We found that reversal of NMB resulted in a faster return to the preoperative status in the Maddox wing test. Patients reported a higher alertness VAS in sugammadex group compared with the others.