COVER SHEET

Title: Optimizing Post-operative Recovery in Bariatric Patients with Obstructive Sleep Apnea Following Outpatient Surgery: A Comparison of Sugammadex and Neostigmine

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Methods:

Subjects: We will obtain approval from the Institutional Review Board at UCSD. One hundred subjects will be enrolled in this study. To be included in this study, subjects must be obese (body mass index [BMI] >30 kg/m^2) with a concurrent diagnosis of OSA (with or without continuous positive airway pressure [CPAP] use), scheduled for surgery requiring general anesthesia and neuromuscular blockade at the UCSD Koman Outpatient Pavilion. Subjects will be excluded from this study if they have a history of hepatic, renal, or cardiovascular and/or cerebrovascular dysfunction, history of difficult tracheal intubation, or adverse reaction to anesthesia. Subjects with a known or suspected adverse reaction to rocuronium, sugammadex, and/or neostigmine/glycopyrrolate will also be excluded. Subjects will be randomized to receive sugammadex (Group S), or neostigmine/glycopyrrolate (Group NG), for reversal of rocuronium-induced neuromuscular block.

Pre-anesthesia: On the day of surgery, an 18 or 20G peripheral IV will be placed in the subjects upper extremity by the preoperative nurse prior to movement to the operating room. Prior to transport to the operating room, baseline spirometry measurements will be taken, along with an arterial blood gas measurement. Baseline vital signs including heart rate, blood pressure, temperature, respiratory rate and pulse oximetry will be recorded.

Induction and Maintenance of Anesthesia: No pre-medications (including midazolam) will be administered. We will position each subject on the operating table and administer 100% oxygen via face-mask. We will apply standard monitors including EKG, non-invasive blood pressure, and pulse oximetry. We will also record End-tidal CO2 measurements via capnography. We will administer the following medications to each subject for induction of general anesthesia: fentanyl 3 mcg/kg LBW, propofol 2.5 mg/kg LBW, and succinylcholine 1 mg/kg TBW. The trachea will be intubated and we will maintain anesthesia with an admixture of oxygen/air and 1-1.2 MAC of sevoflurane. We will use processed EEG to monitor depth of anesthesia. Rocuronium will be administered to achieve deep neuromuscular block (titrated to 0/4 twitches on train-of-four monitoring). Each subject will receive odansetron 4 mg IV and dexamethasone 8 mg IV for prevention of PONV.

Reversal of Neuromuscular Block and emergence: Ten minutes prior to planned extubation, subjects will be given sugammadex 2 mg/kg TBW (Group S) or neostigmine 0.07 mg/kg TBW and glycopyrrolate 0.2 mg for every 1 mg of neostigmine administered (Group NG), depending on pre-procedural randomization. Reversal agents will be administered only after the Train-of Four ratio demonstrates the recovery of at least two twitches. The reversal agents will be pre-drawn so that the anesthesiologist in charge of care is blinded to both the reversal agent and subject randomization. Five minutes following reversal of the neuromuscular block the remifentanil infusion will be discontinued. Extubation will occur once the subject has exhibited extubation criteria as deemed appropriate by standard of care guidelines (stable hemodynamics, stable respiratory mechanics, airway protection).

Post-anesthesia Care: Subjects will be brought to the post-anesthesia care unit (PACU) by the blinded anesthesiologist. A second blinded assessor will record heart rate, blood pressure, temperature, pulse oximetry, observer-assessment sedation scores and subject subjective nausea and pain scores immediately upon PACU admission and every 20 minutes thereafter. Thirty minutes after PACU admission an arterial blood gas measurement will be taken, as well as spirometry measurements. The time to PACU discharge readiness will be recorded by a PACU nurse who will be blinded to subject randomization.

Statistical Analysis:

Assuming a normal distribution of continuous data, the paired T-test will be used to compare times to PACU discharge as well as pre- and post-operative spirometry values, ABG measurements, and vital signs both between and within groups. Categorical data (nausea yes/no) will be compared using the Chi-square test.