This open label dose optimization study of dual-stage 30min ABP-700 infusion regimens was performed in 56 subjects in combination with bolus FEN pre-treatment (n = 32) or REMI co-infusions (n = 24). A total of 8 cohorts of 4 or 8 subjects were completed. Doses were selected based on previous studies to produce sub-hypnotic through occasional deep sedative effect.
Safety assessments included clinical labs, hemodynamic, respiratory and adverse event (AE) monitoring. PD effect was measured using MOAA/S and the BIS monitor.
Results and discussion: Subjects were male (48%) or female (51%) and predominantly white (89%) with ages ranging from 18-55 years. ABP-700 was safe and well tolerated with the majority of AEs reported as mild. At the lowest dose tested, mild BIS deflections were recorded but not associated with clinical sedation effect. Escalating dose regimens demonstrated a steep dose dependent increase in sedation effect as measured by both BIS and MOAA/S. For subjects who were deeply sedated (MOAA/S <2), co-infusion of REMI resulted in apnea in 3 subjects but in none of the subjects receiving FEN pre-medication.
Recovery was rapid accross all cohorts tested with 100% of subjects fully recovered within 10min of infusion completion.
Conclusions: ABP-700 was safe and well tolerated at all doses tested. Dose dependent PD effect was observed with escalating doses of ABP-700. FEN or REMI administration did not significantly alter the profile of ABP-700. Respiration was generally well preserved with apnea events occurring infrequently in deeply sedated subjects receiving REMI. These data suggest that ABP-700 can safely produce levels of sedation ranging from light/moderate to deep and support the further exploration of ABP-700 in a procedural sedation setting.

01AP01-4

Comparison of deep vs. moderate neuromuscular blockade on low-pressure pneumoperitoneum for laparoscopic cholecystectomy

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Background and Goal of Study: Clinical and experimental studies have reported outcome advantages of low-pressure (<9mmHg) vs. standard-pressure (12-14 mmHg) pneumoperitoneum for laparoscopic surgery. However, working with low-pressure pneumoperitoneum can limit working space and surgical conditions could be worse.
The aim of this study was to assess the influence of neuromuscular blockade(NMB) depth on performing low-pressure pneumoperitoneum laparoscopic cholecystectomy(LC)
Materials and methods: Randomized, double blinded clinical trial. Ninety patients scheduled for elective LC were randomly allocated into three groups: Group 1: low-pressure LC (8mmHg) with deep NMB (TOF 0, PTC <5);
group 2: low-pressure LC (8mmHg) with moderate NMB (TOF 1-3) and
group 3: standard-pressure LC (12 mmHg) with no NMB depth pre-determined (control group).
Three experienced surgeons (blinded to intraabdominal pressure (IAP) setting) performed all the surgeries and judged surgical conditions according to a 4-step scale (from 1-optimal to 4-not acceptable, the surgery cannot be performed in these conditions). Operating time and intraoperative complications were investigated. Rocuronium was used for NMB and sugammadex was used for reversal of NMB. Acceleromiography was used for NMB monitoring (TOF-WATCH-S).
Results and discussion: Group 3 showed statistically better surgical conditions ($p=0.021$ Chi^2) and a higher proportion of optimal conditions ($p=0.007$ Chi^2) than groups 1 and 2. No differences on surgical conditions ($p=0.236$ Chi^2) or operating time ($p=0.737$ t test) were observed between groups 1 and 2.
Four patients in group 1 and one patient in group 2 had bad surgical conditions (scoring 4) and IAP needed to be increased to 12 mmHg in order to perform the surgery ($p=0.353$ Fisher). No cases scoring 4 were observed in group 3.
No complications of bleeding or bile duct injury were observed, however the rate of gallbladder perforation was higher at low-pressure LC (groups 1 and 2) when compared to standard-pressure LC (group 3) ($p=0.018$ Chi^2).
Conclusion(s): We did not observe better surgical conditions when performing low-pressure LC with deep NMB compared with moderate NMB. The rate of bad surgical-conditions and complications, patients that needed to increase the IAP for performing the surgery and operating time were not different at both NMB levels. Surgical conditions were judged better when performing LC at 12 mmHg pneumoperitoneum than at 8 mmHg, unrelated to NMB level.

01AP01-5

The effect of deep versus moderate neuromuscular block on postoperative respiratory function in bariatric laparoscopic surgery: a randomized, double blind clinical trial

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Background and Goal of the Study: In recent literature it is has been suggested that deep neuromuscular block (NMB) improves surgical conditions during laparoscopy. The effect of deep NMB on postoperative respiratory function was not investigated in laparoscopic bariatric surgery. We investigated the respiratory function after anaesthesia with deep NMB and moderate NMB. This study was funded by MSD.
Materials and methods: Eligible patients were >18 years of age and were obese (BMI>30kg/m²) or morbidly obese (BMI>40kg/m²) and scheduled to undergo laparoscopic gastric bypass surgery. Patients were stratified according to their BMI and evenly randomized over a deep NMB-group (rocuronium bolus and infusion maintaining a posttetanic count of 1-2, reversal with sugammadex 4mg/kg) and a moderate NMB-group (rocuronium bolus and top-ups maintaining a train-of-four count of 1-2, reversal with neostigmine 50μg/kg and glycopyrolate). Anaesthesia was induced and maintained with propofol and remifentanil. In both groups patients were extubated when the TOF-ratio was >0.9. The primary outcome measure was the postoperative pulmonary function assessed by peak expiratory flow (PEF), forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC) and measured with an electronic portable peak flow meter. Data are presented as mean±SEM.
Results and discussion: After IRB approval and obtaining informed consent, 60 patients were included in the study. After surgery, all the pulmonary function tests were considerably impaired in both groups when compared to baseline (see Table 1). There was no statistically significant difference in the decrease in PEF, FEV1 and FVC (expressed as % change from baseline) between the deep and the moderate NMB-group (51.3±6.0% *vs.* 51.5±3.5%; P=0.97, 45.2±6.9% *vs.* 48.8±3.6%; P=0.64, 51.9±3.1% *vs.* 49.0±4.2%; P=0.29, respectively). In the deep NMB-group, 2 patients required postoperative non-invasive CPAP *vs*. 1 patient in the moderate NMB-group (P=0.6). No patient needed reintubation after surgery.

Pulmonary function tests	Deep NMB-group		P-value	Moderate NMB-group		P-value
	Pre-operative	Post-operative		Pre-operative	Post-operative	
PEF (l/min)	314±20	141±15	P<0.0001	276±15	126±0.1	P<0.0001
FEV1 (l)	2.4±0.2	1.1±0.1	P<0.0001	2.2±0.1	1.1±0.1	P<0.0001
FVC (l)	3.0±0.2	1.4±0.1	P<0.0001	2.7±0.1	1.2±0.1	P<0.0001

[Table 1. Pulmonary function tests]

Conclusions: Pulmonary function is significantly impaired after laparoscopic bariatric surgery irrespective of the NMB-regime as long as NMB is adequately monitored and reversed at the end of surgery.