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Low-pressure pneumoperitoneum with deep neuromuscular blockade in metabolic surgery to reduce postoperative pain: a randomized pilot trial

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Abstract

Background For metabolic laparoscopic surgery, higher pressures up to 20 mmHg are often used to create a surgical field of sufficient quality. This randomized pilot study aimed to determine the feasibility, safety and tolerability of low intraabdominal pressure (IAP) and deep neuromuscular blockade (NMB) to reduce postoperative pain.

Methods In a teaching hospital in the Netherlands, 62 patients eligible for a laparoscopic Roux-en-Y gastric bypass (LRYGB) were randomized into one of four groups in a 2 × 2 factorial design: deep/moderate NMB and standard (20 mmHg)/low IAP (12 mmHg). Patient and surgical team were blinded. Primary outcome measure was the surgical field quality, scored on the Leiden-Surgical Rating Scale (L-SRS). Secondary outcome measures were (serious) adverse events, duration of surgery and postoperative pain.

Results 62 patients were included. L-SRS was good or perfect in all patients that were operated under standard IAP with deep or moderate NMB. In 40% of patients with low IAP and deep NMB, an increase in IAP was needed to improve surgical overview. In patients with low IAP and moderate NMB, IAP was increased to improve surgical overview in 40%, and in 75% of these cases a deep NMB was requested to further improve the surgical overview. Median duration of surgery was 38 min (IQR34-40 min) in the group with standard IAP and moderate NMB and 52 min (IQR46-55 min) in the group with low IAP and deep NMB.

Conclusions The combination of moderate NMB and low IAP can create insufficient surgical overview. Larger trials are needed to corroborate the findings of this study.

Trial registration: Dutch Trial Register: Trial NL7050, registered 28 May 2018. https://www.trialregister.nl/trial/7050.

Keywords Low-pressure pneumoperitoneum · Neuromuscular block · Gastric bypass · Postoperative pain · Surgical overview · Working space

Many published papers describe the advantages and side effects of laparoscopy in the surgical obese patient [1–5]. Currently, laparoscopy is considered the golden standard in metabolic surgery [6]. Guidelines on laparoscopy recommend to operate under the minimum intraabdominal pressure (IAP) needed for a good overview, ranging from seven to 19 mmHg [7]. In obese patients, higher pressures up to 20 mmHg are sometimes used to create a surgical field of sufficient quality [8]. However, a recent systematic review and meta-analysis has shown that higher IAPs might increase postoperative pain [9]. Therefore, patients undergoing metabolic surgery should preferably be operated with lower IAPs, while maintaining a good quality of the surgical field, and without increasing the number of adverse events.

Over the years, the technique of deep neuromuscular blockade (NMB) to create more surgical working space has gained popularity. This popularity has increased further

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due to the availability of Sugammadex, a selective relaxant-binding agent that can rapidly reverse neuromuscular blockade. It has been shown to be effective and to reduce the duration of surgery and the incidence of residual block during recovery [10]. Recent studies have shown that deep NMB can also be a promising technique for metabolic procedures [11–13]. However, the optimal combination of depth of NMB and amount of IAP in metabolic surgery has not yet been determined. As fast-track protocols are becoming more popular in metabolic surgery, it is important to determine the most optimal combination of IAP and NMB for this specific patient population.

Our research hypothesis is that patients undergoing metabolic surgery with deep NMB and low IAP compared to moderate NMB and standard IAP will have less postoperative pain, without causing deterioration of the surgical field or an increase in duration of surgery or complication rate. This could lead to an increase in patient satisfaction and potentially a decrease in costs due to shorter length of hospital stay, less usage of analgesia and less revisits to the emergency ward. The aim of this randomized pilot study is to evaluate the feasibility, safety and tolerability of standard- versus low-pressure pneumoperitoneum and deep versus moderate NMB.

Methods

Study design and participants

This was a randomized single center pilot study comparing the effects of deep versus moderate NMB and standard versus low IAP in a 2 × 2 factorial design from September 2018 to March 2019 in a teaching hospital in the Netherlands. All patients found suitable for metabolic surgery according to the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) guidelines and undergoing a primary laparoscopic Roux-en-Y gastric bypass (LRYGB) were invited for study participation. Patients were excluded in case of allergies for used medication, neuromuscular comorbidities, a medical history of pain disorders such as abdominal cutaneous nerve entrapment syndrome (ACNES), fibromyalgia or complex regional pain syndrome (CRPS), or if they were unwilling or unable to give informed consent. All patients were treated according to the Enhanced Recovery After Bariatric Surgery (ERABS) protocol as earlier described by Mannaerts et al., which is the standard protocol for all patients undergoing metabolic surgery in this center [14]. This protocol describes usage of standard IAP and moderate NMB.

No formal sample size calculation was done for this pilot study. We included a convenience sample of 60 patients, fifteen patients per group. Later, eight more patients were included to make up for the patients that had to be excluded during the study period. The study protocol was approved by the institutional review board (IRB) and the regional Medical Research Ethics Committee MEC-U, Nieuwegein, the Netherlands. The study was registered in the Dutch Trial Register on 28 May 2018 (Trial NL7050).

Blinding and randomization

After obtaining informed consent at the outpatient clinic of the departments of surgery or anesthesiology, patients were randomized by the principal investigator into one of four groups using variable block randomization software (Castor EDC©) without stratification (randomization ratio 1:1:1:1). Figure 1 shows the treatment protocol. Patients received either deep or moderate NMB and either standard or low IAP. During the time-out procedure (TOP), the anesthesiology team verified the group of randomization and carried out the treatment accordingly. Patient and surgical team were blinded for the treatment, by covering the display of the pressure meter and the train-of-four (TOF) or post-tetanic count (PTC) measurements. Additionally, the surgeon left the operating room for ten minutes after the TOP to ensure blinding. The anesthesiologist, who cannot be blinded, coordinated the depth of NMB and adjusted parameters in case of emergency.

Perioperative management

The regular anesthesia policy was described earlier by Mannaerts et al. and includes preoperative administration of analgesia and anti-emetics [14]. For this study, patients in all four study groups received an induction dose of 30 mg rocuronium. In patients receiving moderate NMB, the depth of the NMB was sufficient with a TOF ratio of 1–2. It was kept in that range during surgery with incremental doses of rocuronium when necessary, with an anticipated dose of 30–130 mg. For patients receiving deep NMB, additional rocuronium bromide was administered after induction, until the PTC was between one and two twitches. The PTC was kept in that range during surgery with incremental doses of rocuronium when necessary, with an expected average dose of 70 mg after induction, and a range of total rocuronium between 45 and 145 mg. Both types of neuromuscular blockades were reversed with Sugammadex, of which the anticipated dose was 100–200 mg in moderate NMB and 180–370 mg in deep NMB. This protocol largely corresponds to the one published by Torensma et al. [12].

All treatment groups underwent a LRYGB as described by Leiffson et al. [15]. The standard IAP for metabolic surgery in our center is 20 mmHg, which is possibly higher compared to other centers performing metabolic procedures. However, because of the short duration of surgery within the

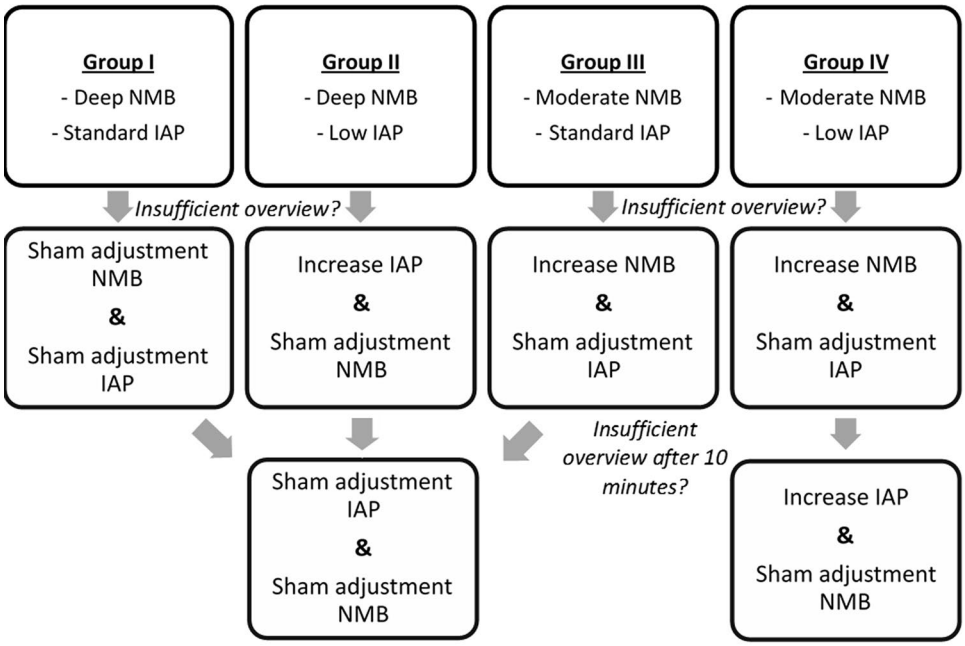

Fig. 1 Treatment protocol and escape plan in case of insufficient surgical field quality

ERABS protocol, we do not experience higher complication rates, specifically not those that are associated with a standard IAP. For low IAP, a pressure of 12 mmHg was used. In case of insufficient surgical overview, an 'emergency plan' was set up in which the surgeon could ask for a maximum of two adjustments (Fig. 1). When requested by the surgeon, the anesthesiologist was able to either increase the NMB to 'deep' or increase IAP to 'standard'. In case the patient was already receiving deep NMB and standard IAP, a sham 'improvement' was performed by the anesthesiologist and the surgeon continued the procedure when assumed safe.

Outcome measures

The primary outcome measure was feasibility or the overview of the surgical field. Directly after the procedure, the surgeon evaluated the overall quality of the surgical field on the Leiden-Surgical Rating Scale (L-SRS), ranging from 1 (extremely poor quality) to 5 (perfect quality). An extra evaluation of the surgical field was performed in case of peroperative alterations to either IAP or NMB due to insufficient surgical overview. Secondary outcome measures were (1) tolerability or postoperative pain until 7 days postoperative, for which the patient kept a daily pain diary to score the pain of the wound, shoulder and intraabdominal pain and register the used analgesia on a daily basis. A minimal clinically relevant difference in mean pain scores (at the group level) was defined as a difference of at least 3% of the score range, or $0.03*4=0.12$. (2) safety, in terms of (serious) adverse events ((S)AEs) and (3) duration of surgery. To obtain as many responses as possible after discharge, patients were contacted on the fourth postoperative day to inform on their well-being and pain scores. Patients were contacted again after receiving back their pain dairy for confirmation of arrival of the study papers and to answer possible questions about their treatment.

Statistical analysis

Data management was performed in Castor EDC. Data were analyzed using SPSS (PASW) version 25 software (SPSS Inc., Chicago, Illinois, USA). Duration of surgery was reported in mean ± SD. Multiple linear regression analysis was used to estimate the impact of NMB and IAP on the L-SRS score and duration of surgery as dependent variables and NMB (deep/moderate) and IAP (standard/low) and the interaction effect of NMB and IAP as covariables. Repeated measurements analysis (linear mixed model) was used to estimate/quantify the impact of NMB and IAP on pain (covariance structure: unstructured). Dependent variable was the pain score, independent variables were time, NMB (deep/moderate), IAP (standard/low), and the baseline pain score, age, sex and preoperative body mass index (BMI) as covariables. In a secondary analysis, dependent variable was the pain score, independent variables were time, complication (present/absent), the four treatment groups (three dummy variables) and the baseline pain score, age, sex, and preoperative BMI as covariables.

Results

Figure 2 shows the trial profile. In total, 68 patients were included in the study between September 2018 and March 2019. After this, the trial stopped because of reaching the required number of participants. Three patients withdrew consent and their data were removed. One patient was excluded because the surgery was postponed for personal reasons. Excluded were two patients with severe comorbidities; the anesthesiologist advised against surgery and trial participation. Table 1 shows the baseline characteristics of the 62 included patients. For four patients, the exact level of NMB was uncertain because of a malfunctioning TOF/PTC measuring device. For three patients, the decision was made peroperatively to perform a mini gastric bypass (MGB) instead of a LRYGB due to poor quality of the small intestines.

Table 2 shows the mean L-SRS scores by group. In patients that were operated with standard IAP, the L-SRS

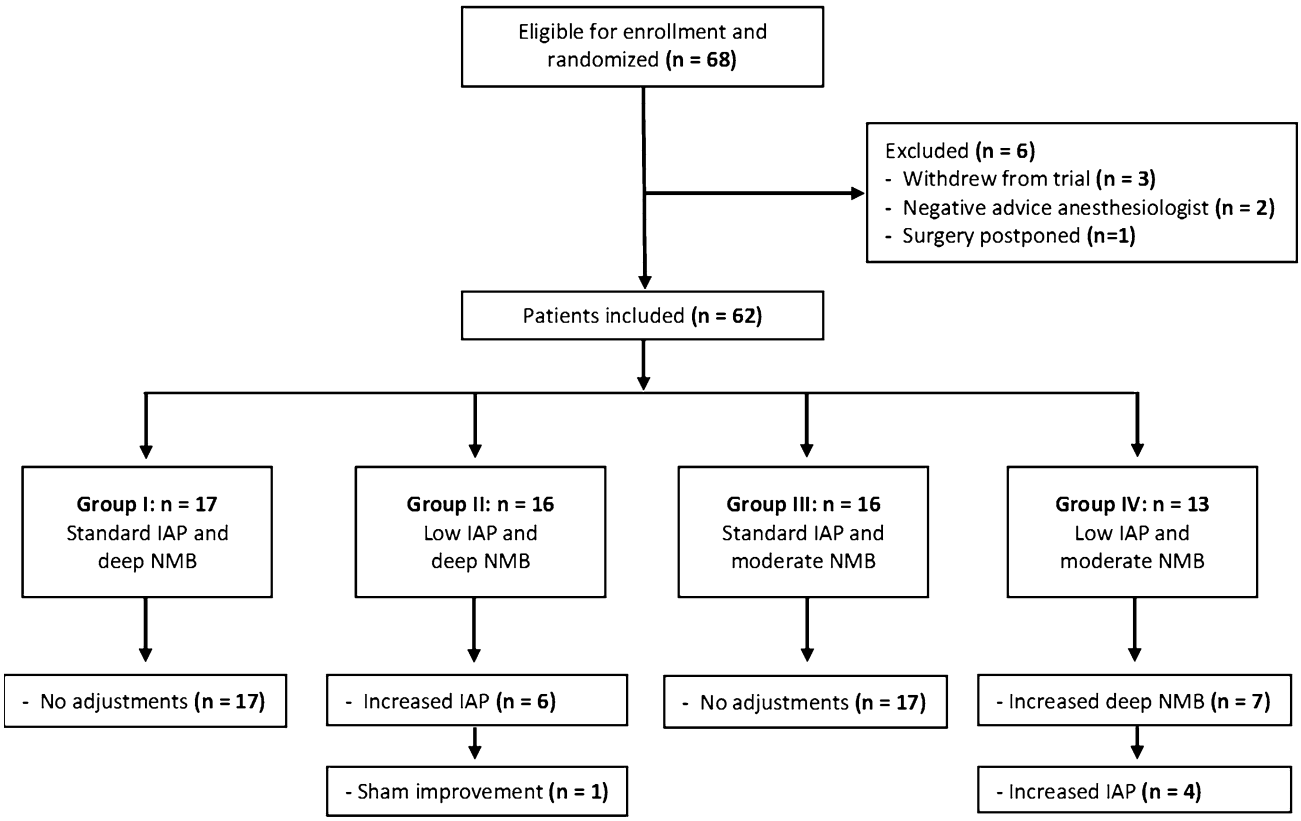

Fig. 2 Trial profile

Table 1 Baseline characteristics

	Group I: Standard IAP + deep NMB ($n = 17$)	Group II: Low IAP + deep NMB ($n = 16$)	Group III: Standard IAP + mod NMB ($n = 16$)	Group IV: Low IAP + mod NMB ($n = 13$)
Female, *n* (%)	10 (58.8%)	14 (87.5%)	14 (87.5%)	13 (100%)
Age (years), mean ± SD	49 ± 12	48 ± 13	43 ± 11	49 ± 8
Baseline BMI (kg/m^2), mean ± SD	39.11 ± 3.91	40.54 ± 3.53	41.66 ± 5.44	44.4 ± 5.10
Waist circumference (cm), mean ± SD	126.4 ± 9.6	126.0 ± 8.6	126.2 ± 11.0	129.2 ± 8.5
Presence of T2D, *n* (%)	6 (35.3%)	3 (18.8%)	2 (12.5%)	1 (7.7%)
Presence of hypertension, *n* (%)	12 (70.6%)	7 (43.8%)	9 (56.3%)	5 (38.5%)
Presence of dyslipidemia, *n* (%)	5 (29.4%)	7 (43.8%)	5 (31.3%)	6 (46.2%)

BMI body mass index, *IAP* intraabdominal pressure, *NMB* neuromuscular blockade, *SD* standard deviation, *T2D* type 2 diabetes

Table 2 Surgical overview (L-SRS) without adjustments (mean ± SD)

	Group I: standard IAP + deep NMB ($n = 17$)	Group II: Low IAP + deep NMB ($n = 16$)	Group III: Standard IAP + mod NMB ($n = 16$)	Group IV: Low IAP + mod NMB ($n = 13$)
L-SRS without adjustments, mean ± SD	4.94 ± 0.24	3.50 ± 1.03	4.75 ± 0.45	3.62 ± 1.04
First adjustment, *n* (%)	0 (0.0%)	6 (37.5%)	0 (0.0%)	7 (53.8%)
L-SRS after adjustment		*3.71 ± 0.76*		*3.14 ± 0.90*
Second adjustment, *n* (%)	0 (0.0%)	1 (6.3%)	0 (0.0%)	4 (30.8%)
L-SRS after adjustment, mean ± SD		*3.00*		*4.00 ± 0.82*

L-SRS Leiden-surgical rating scale, *IAP* intraabdominal pressure, *NMB* neuromuscular blockade, *SD* standard deviation

was always scored 4/5 (good) or 5/5 (perfect) and no adjustments were requested. In patients with low IAP and deep NMB (group II), 37.5% needed an increase in IAP to improve surgical overview. In patients with low IAP and moderate NMB (group IV), 53.8% needed a primary adjustment (deeper NMB) to improve surgical overview, after which a second adjustment (increase IAP) was requested in 57.1% of these cases. Overall, L-SRS scores increased on average + 1.352 (95% CI 0.985–1.719) when using standard instead of low IAP and L-SRS scores decreased on average − 0.126 (95% CI − 0.494 to 0.242) when using moderate instead of deep NMB.

Figure 3 shows the mean durations of surgery for the four groups. The duration of surgery increased on average with + 4.3 min (95% CI − 0.3; 8.9 min) when using moderate instead of deep NMB and the duration of surgery decreased on average with − 8.9 min (95% CI − 13.6; − 4.3 min) when using standard instead of low IAP.

Regarding safety, three SAEs occurred. In patient #1 in group I with standard IAP and deep NMB, surgical overview was perfect. This patient was readmitted 1 day after discharge and was reoperated to evacuate an intraabdominal hematoma. In patient #2 in group IV with low IAP and moderate NMB, because of malfunctioning of the TOF/PTC measure device, the IAP was increased to 20 mmHg, after which the L-SRS was scored 5. This patient underwent a reoperation due to a staple line leakage at the gastro-enterostomy. The patient was later excluded due to the malfunctioning device. Patient #3, operated with standard IAP and deep NMB (group I), had a L-SRS score of 5. This patient underwent a reoperation, in which three iatrogenic bowel defects were detected and sutured. All patients recovered well. The SAEs were reported to the MEC-U.

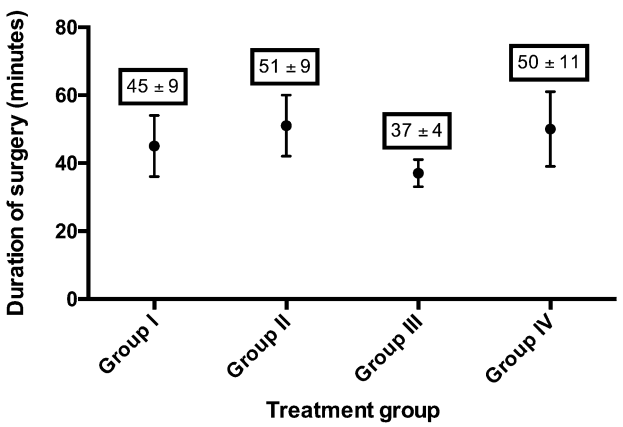

Fig. 3 Duration of surgery in minutes per treatment group* (mean ± SD). *Group I: Standard IAP + deep NMB; Group II: Low IAP + deep NMB; Group III: Standard IAP + mod. NMB; Group IV: Low IAP + mod. NMB. Abbreviations: *IAP* intraabdominal pressure, *NMB* neuromuscular blockade, *SD* standard deviation

Figure 4 shows the pain scores over time for 53/62 (85.5%) patients. Three out of the 62 patients did not keep pain diaries after they developed early postoperative complications. There is no information on the reason for lost to follow-up for the other patients. Analgesia usage on day 4 postoperatively was 61% in group 1, 73% in group II, 50% in group III and 80% in group IV. The usage of analgesia was positively correlated with the reported pain scores.

Tables 3 and 4 show the results of the repeated measurements analysis of shoulder pain, superficial pain or deep abdominal pain over time. After correcting for several covariables, pain scores on shoulder pain were slightly higher in group I (standard IAP + deep NMB) and in group II (low IAP + deep NMB) compared group IV (low IAP + moderate NMB).

Discussion

In this randomized pilot study, we compared the effects of low (12 mmHg) or standard (20 mmHg) IAP and moderate or deep NMB on surgical overview, complications and postoperative pain in LRYGB surgery. The results display that in patients operated with low IAP, the surgeon evaluated the surgical overview insufficient in 40% of cases, suggesting low feasibility. Furthermore, patients operated

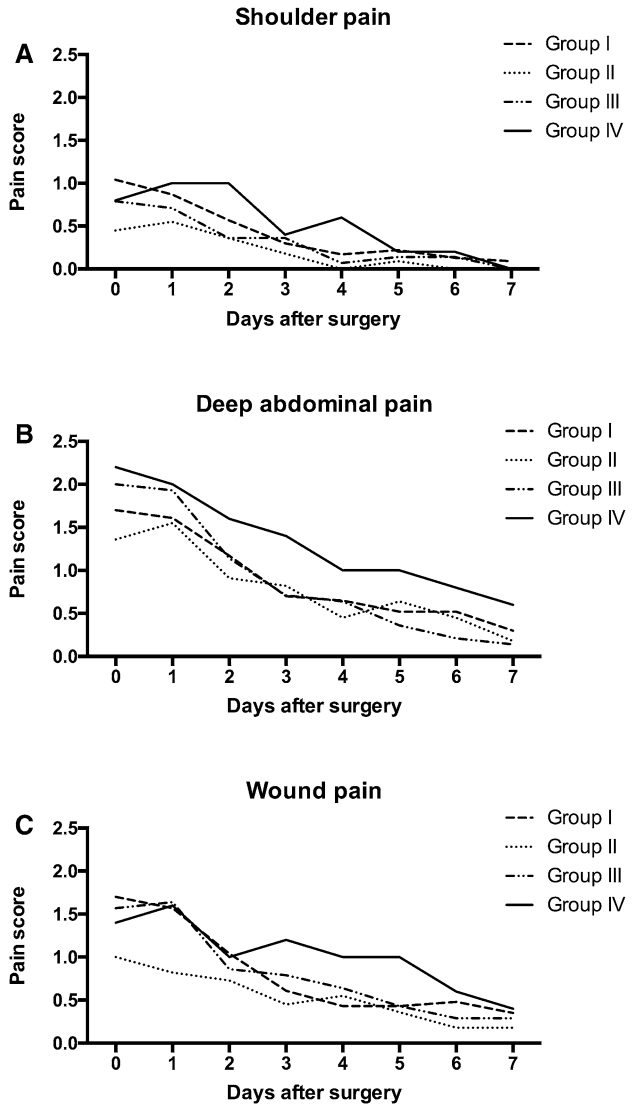

Fig. 4 **A** Shoulder pain*. **B** (Superficial) wound pain*. **C** (Deep) abdominal pain*. *Group I: Standard IAP + deep NMB; Group II: Low IAP + deep NMB; Group III: Standard IAP + mod. NMB; Group IV: Low IAP + mod. NMB. Abbreviations: *IAP* intraabdominal pressure. *NMB* neuromuscular blockade

with low IAP and moderate NMB scored slightly higher on postoperative pain compared to standard IAP.

Surgeons requested for an adjustment in nearly half of the patients that were randomized in the low IAP groups. In our center, an IAP of 20 mmHg is standard protocol for metabolic fast-track surgery. Surgeons might have accustomed to a spacious surgical overview, making the decrease in intraabdominal working space easily noticeable. Nevertheless, this decrease in working space might not necessarily lead to an increase in surgical difficulty or an increase in complication rates. The optimal

Table 3 Individual effects of NMB and IAP on pain scores

	Estimate	95% CI	Sig
Shoulder pain			
NMB: Moderate vs deep	− 0.097	− 0.166; − 0.028	< 0.001
IAP: Low vs standard	− 0.037	− 0.166; 0.038	0.325
Superficial (wound) pain			
NMB: Moderate vs deep	0.061	− 0.155; 0.278	< 0.001
IAP: Low vs standard	− 0.034	− 0.274; 0.207	0.780
Deep intraabdominal pain			
NMB: Moderate vs deep	0.037	− 0.206; 0.279	0.762
IAP: Low vs standard	0.161	− 0.098; 0.420	0.217

Score range: 0–4 All analysis adjusted for time (day postoperative, pain at T0, age, sex, BMI preoperative) and NMB (deep/moderate) and IAP (standard/low)

BMI body mass index, *IAP* intraabdominal pressure, *NMB* neuromuscular blockade, *CI* confidence interval

intraabdominal pressure for metabolic (fast-track) surgery has not yet been determined. Other studies that address the optimal IAP in metabolic surgery describe a wide range of used IAP from 14 to 18 mmHg [8, 11, 12, 16, 17] which points to large practice variation.

The duration of surgery increased when using moderate NMB and decreased when using standard IAP. This result is in line with the results from previous studies, describing that deep NMB can shorten the duration of surgery due to an improved surgical overview and that the deep muscle relaxation can easily and quickly be reversed with the use of Sugammadex [10, 18]. Gaining nine minutes of operating time is substantial for the RYGB procedures, as this could result in the possibility to perform one extra procedure per day.

The effects of moderate versus deep NMB were also investigated in this trial, which were based on the TOF or PTC measurements. During the 10 min in which the surgeon left the OR, the planned depth of NMB was reached and the procedure started. Unfortunately, the depth of NMB was sometimes difficult to manage, as each patient responded to the administered rocuronium at a different speed. The total costs of the procedure can vary between the patients and the patient groups because of the differences in duration of surgery and the amount of NMB medication. However, these costs were not taken into account in this pilot study.

The L-SRSs were scored by four different surgeons and could therefore be vulnerable to inter-surgeon and intra-surgeon variability. As the L-SRS is a subjective score, it could also be biased by the position of trocars or the quality of the camera imaging. The score was an overall evaluation of the surgical field. Torensma et al. chose to score the L-SRS every ten minutes, with the aim to increase accuracy [12]. Nevertheless, the changes in L-SRS during a procedure were mainly related to the more complex part of the procedure. As the L-SRS scores

Table 4 Differences between groups in pain scores* estimated with repeated measures analysis** (reference, group IV: low IAP + moderate NMB)

	Estimate	95% CI	Sig
Shoulder pain			
Standard IAP + deep NMB vs. reference	0.154	0.030; 0.228	0.016
Low IAP + deep NMB vs. reference	0.148	0.012; 0.285	0.034
Standard IAP + moderate NMB vs. reference	0.093	− 0.037; 0.222	0.155
Superficial (wound) pain			
Standard IAP + deep NMB vs. reference	− 0.176	− 0.545; 0.193	0.343
Low IAP + deep NMB vs. reference	− 0.417	− 0.823; − 0.012	0.044
Standard IAP + moderate NMB vs. reference	− 0.227	− 0.613; 0.159	0.242
Deep intraabdominal pain			
Standard IAP + deep NMB vs. reference	− 0.279	− 0.703; 0.145	0.192
Low IAP + deep NMB vs. reference	− 0.331	− 0.803; 0.142	0.165
Standard IAP + moderate NMB vs. reference	− 0.308	− 0.751; 0.135	0.168

*Score range: 0–4

**All analyses adjusted for time (day postoperative, pain at T0, age, sex, BMI preoperative) and treatment group

BMI body mass index, *IAP* intraabdominal pressure, *NMB* neuromuscular blockade, *CI* confidence interval

of the Torensma study are similar to the results from our pilot study, repeated L-SRS scores present no advantage over one overall surgical overview score we used to judge feasibility.

Three SAEs occurred. All of these patients were operated under sufficient surgical overview. Therefore, these complications do not seem directly related to study participation or allocated treatment. We conclude that safety is not compromised by study participation. However, the occurrence of an SAE is likely to bias the pain scores of the patients. As no pain scores were available from the patients that had a SAE in this trial, no conclusions can be formed on the effect of an SAE on the pain scores.

A limitation of this pilot study is the fact that no formal sample size calculation was done. We aimed to do a pilot study, in order to use these results for the sample size calculation of the planned larger randomized controlled trial. However, we felt that it was contributing to analyze the results of this pilot study and carefully draw conclusions, which we hope to further support in a future trial. Another limitation is the lack of data of patients who had a SAE. According to the intention-to-treat analysis, we would want to analyze the pain scores of these patients as well. The effect of an SAE on pain scores should be evaluated in a future trial. This future trial could also focus more on the cost-effectiveness of the different combinations of IAP and NMB.

Even though the patients were randomized, there were significant differences in gender and presence of T2D between the groups. These differences could potentially affect the pain scores. The abdominal wall thickness and visceral fat volume of men may differ from those of women, and might influence the ease of the operation and herewith the needed IAP. Also the presence of T2D could be correlated to fat deposition and the ease of the operation. In a future study, homogeneous groups should be stratified in order to rule out these potential biasing factors.

Across the four groups, we saw no great differences in pain scores and used analgesia, but patients operated with low IAP and moderate NMB scored slightly higher on postoperative pain compared to standard IAP. This difference was no longer present after correcting for patient characteristics and pain score on T0. Pain scores can be difficult to compare, as each individual experiences and scores pain in a different way. Even though the pain scores were patient-reported, inter-individual differences in pain scores appeared modest. Moreover, in a larger randomized controlled trial, these individual-related factors influencing reporting behavior heterogeneity should be approximately equally divided across the groups and therefore cancel out in between-group differences in pain scores.

Conclusions

The results from our pilot study suggest that a randomized controlled trial comparing the effects of low (12 mmHg) or standard (20 mmHg) IAP and moderate or deep NMB on surgical overview and postoperative pain in LRYGB surgery is feasible, safe and tolerable. The surgical overview was scored insufficient in a substantial percentage of patients operated under low IAP suggesting that 12 mmHg IAP is suboptimal. In a future trial, slightly higher pressures of 14–18 mmHg, e.g., 16 mmHg, may be a good alternative

to compare the effects of IAP on postoperative pain score without risking a deterioration of the surgical overview. An IAP of 16 mmHg is used more frequently in metabolic surgery and therefore the results can be relevant. Factors that can influence the subjective L-SRS scores and pain scores, such as operator and individual-related factors, should be taken into account. Furthermore, a negative advice from the anesthesiologist to participate in a trial should be added to the exclusion criteria. Further larger trials are required to test the findings of this pilot study.

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Compliance with ethical standards

Disclosures Drs. Leeman, Drs. Biter, Drs. Apers, Dr. Birnie, Dr. Verbrugge and Dr. Dunkelgrun have no conflicts of interest or financial ties to disclose.

Ethics approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. The study protocol was approved by the institutional review board (IRB) and the regional Medical Research Ethics Committee TWOR, Rotterdam, the Netherlands (Registration Number NL64025.101.17 and Protocol Number 2018–80).

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