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The effect of moderate versus deep neuromuscular blockade on the surgical rating scale in laparoscopic sleeve gastrectomy in a Malaysian tertiary university hospital: a randomised clinical trial

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Abstract

Background: The depth of neuromuscular blockade (NMB) is important to provide optimal space during laparoscopic surgery, especially in the obese population. This study compared the effects of moderate versus deep neuromuscular blockade on the surgical rating scale in laparoscopic sleeve gastrectomy.

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Methods: This single-blind, randomised controlled trial involved 24 patients with a body mass index > 30 kg/m^2 who underwent laparoscopic sleeve gastrectomy. They were randomised into two groups: moderate NMB with a target train-of-four (TOF) of 1-2 (Group M) and deep NMB with a post-tetanic count (PTC) of 1-2 (Group D). The quality of the surgical field was scored by a surgeon using the 5-point Surgical Rating Scale (SRS) from 1 (extremely poor condition) to 5 (optimal condition). The haemodynamic changes, end-tidal CO_2, duration of surgery, and intraabdominal pressure were also recorded. At the end of surgery, patients were given intravenous sugammadex at 2 mg/kg if the TOF count was 12, or 4 mg/kg if the PTC was 1-2. Patients were extubated when the TOF ratio (T4/T1) was greater than 0.9.

Results: The mean SRS was significantly higher in Group D (4.83 ± 0.39) compared with Group M (4.08 ± 0.79), *p*-value = 0.004. All patients in Group D had favourable surgical conditions, in which 16.7% of patients achieved SRS of 4 and 83.3% had SRS of 5. In Group M, 8.3% of patients had an unfavourable surgical field.

Conclusion: A deep NMB provided a favourable surgical condition compared with a moderate NMB in the laparoscopic sleeve gastrectomy.

Keywords: gastrectomy, laparoscopic procedure, neuromuscular blockage, satisfaction

Introduction

Obesity is a serious health problem that occurs more commonly nowadays and is usually associated with a series of comorbidities, such as diabetes mellitus and cardiovascular diseases.[1] According to a nationwide survey conducted in Malaysia in 2019, there has been an upward trajectory in the prevalence of obesity. The rates have escalated from 15.1% in 2011 to 17.7% in 2015, ultimately reaching 19.9% in 2019.[2,3] Obesity can be treated medically or surgically. Medically, obesity is treated by diet modifications, regular physical activities, and weight-loss medications.[4] Surgically, a few procedures can be recommended for appropriate patients. These procedures are called bariatric surgeries and can be performed either as an open procedure or laparoscopically. Laparoscopic techniques have become more popular recently because of their multiple benefits, which include a reduction in postoperative pain, smaller surgical scars, shorter hospital stays, and less postoperative pulmonary impairment.[5,6]

The challenges of laparoscopic surgery are numerous, which may include a poor surgical field with inadequate space and volume, especially in an obese population. Studies showed that the routine use of neuromuscular blocking agents up to the level of deep blockade might help overcome these problems.[7] Deep neuromuscular blockade (NMB) was associated with a better surgical condition than moderate muscle relaxation, especially during low-pressure laparoscopic surgery. Laparoscopic surgery performed with an intra-abdominal pressure of 12 to 15 mmHg is associated with fewer deleterious effects on pulmonary function and haemodynamics. However, deep blockade may result in poor recovery of muscle function at the end of surgery. It is associated with the risk of postoperative complications such as prolonged emerging time from anaesthesia, significant impairment of pharyngeal muscle function post-extubation, obtundation of hypoxic ventilatory drive, and reduced respiratory function, particularly in obese patients.[8]

Intraoperatively, the degree of blockade at the neuromuscular junction is monitored with a neuromuscular monitoring device, either with a train-of-four (TOF) count for a moderate block or a post-tetanic count (PTC) for a deep block.[9] In certain circumstances, a deep block (PTC 1–2) is required to achieve good surgical conditions.[10] The routine use of neostigmine as a reversal agent does not guarantee a complete return of neuromuscular function. The introduction of sugammadex, a gamma-cyclodextrin molecule with high affinity for aminosteroidal neuromuscular blocking agents such as rocuronium, can rapidly reverse deep neuromuscular blockade.[11]

This study was conducted to assess the effect of moderate versus deep NMB on laparoscopic sleeve gastrectomy in a single tertiary university hospital in Malaysia. In this study, laparoscopic sleeve gastrectomy was chosen since it is the most common surgery performed in our centre when compared to other types of bariatric procedures such as gastric bypass or gastric banding. It is also the most common type of bariatric surgery performed worldwide.[12] Selecting a single procedure can probably minimise the bias in this study. It was hypothesised that there was no difference in the surgeon's satisfaction and duration of surgery between moderate and deep neuromuscular blockade.

Methods

This was a single-blinded, randomised controlled trial involving 24 patients who underwent laparoscopic sleeve gastrectomy under general anaesthesia from March to October 2016 at a tertiary university hospital. The study was conducted in accordance with the Declaration of Helsinki and approved by the Medical Research and Ethics Committee of Universiti Kebangsaan Malaysia Medical Centre (FF-2015-361). Patients scheduled for the surgery were recruited, and written informed consent was obtained.

Eligible patients were more than 18 years old and obese with a body mass index (BMI) of more than 30 kg/m^2. Patients with coexisting neuromuscular diseases, known hypersensitivity to drugs that were used in this study, liver impairment, significant renal impairment (creatinine clearance < 30 ml/min using Cockcroft-Gault Formula), and previous abdominal surgery or revision of laparoscopic bariatric surgery were excluded from this study. With respect to the degree of NMB, the patients were assigned randomly into two groups: a moderate block with a TOF count of 1–2 (Group M) and a deep block with a PTC of 1–2 (Group D) using a computer-generated randomization code. The code was given to the anaesthesiologists in charge of the patients prior to the induction of anaesthesia.

Standard anaesthetic monitoring was applied throughout the procedure, consisting of non-invasive blood pressure, an electrocardiograph, pulse oximetry, end-tidal carbon dioxide (etCO_2), nasopharyngeal temperature monitoring, and multigas analysers. Additionally, NMB was monitored every 10 minutes with a Neuromuscular Transmission (NMT) Sensor Cable (GE Datex-Ohmeda, Helsinki, Finland). Neuromuscular monitoring was done over the ulnar nerve of the left or right wrist. The mechanosensor was attached to the ipsilateral thumb and second finger with tape. After induction of anaesthesia but prior to administration of muscle relaxants, the device was calibrated to get the supramaximal stimulus. The device started the measurement by setting the stimulus current automatically and by performing a reference measurement.

Prior to induction of anaesthesia, all patients were positioned in the ramped position to achieve optimal intubation conditions. They were given intravenous fentanyl (2 mcg/kg lean body weight, LBW) and propofol (2 mg/kg LBW). Depending on the preoperative airway assessment, muscle paralysis was induced either with intravenous suxamethonium 1.5 mg/kg total body weight (TBW) or rocuronium 0.6 mg/kg ideal body weight (IBW), according to anaesthetist preference. All patients were intubated using a C-MAC® video laryngoscope (Karl Storz GmbH & Co. KG, Tuttlingen Germany). None of the patients required awake fibreoptic intubation. For those patients who received suxamethonium for intubation, a bolus dose of rocuronium (0.6 mg/kg IBW) was given subsequently. Anaesthesia was maintained with a mixture of air, oxygen, and desflurane with a minimum alveolar concentration of approximately 1.0–1.2. All patients received 10 ml of 0.2% ropivacaine as local anaesthesia, intravenous parecoxib 40 mg, and intravenous paracetamol 1g as a standard analgesia.

Patients in Group M were given intravenous rocuronium 10 mg intermittently to achieve a TOF count of 1–2 (moderate block), while in Group D patients received regular boluses of intravenous rocuronium 10 mg every 15–20 minutes with the aim of maintaining PTC 1–2 (deep block).

Each laparoscopic operation in this study was conducted by a surgeon who possessed considerable experience but was unaware of the group allocation. Measurements of blood pressure, heart rate, pulse oximetry, $etCO_2$, and neuromuscular monitoring were recorded every 30 minutes. In addition, the duration of surgery, gas flow, and intra-abdominal pressure were also documented every 30 minutes. The intraabdominal pressure was set at 12 mmHg (low pressure), but in the event of inadequate surgical visibility, the pressure and gas flow were increased accordingly and recorded.

At the end of surgery, all patients were given a reversal agent: intravenous sugammadex, 2 mg/kg corrected body weight (CBW) if TOF count 1–2, or 4 mg/kg CBW if PTC 1–2. Patients were extubated when the TOF ratio (T_4/T_1) was greater than 0.9. The definitions of IBW, TBW, LBW, and CBW are listed in Appendix 1.

An evaluation form was handed to the surgeon after the completion of surgery to evaluate the level of satisfaction and the ease of surgery in both groups of patients. The 5-point Surgical Rating Scale (SRS) (Appendix 2) was used based on a previous study done by Martini *et al.* SRS of 4 or 5 was considered a favourable condition for laparoscopic surgery.

Statistical analysis

The sample size was calculated with reference to Martini *et al.*, who concluded that the rating during a moderate block is 30% in the SRS of 4 or 5, and the rating during a deep block is 90% in the SRS of 4 or 5.[13] The α-value was set at 5% and the power of study at 80%. A sample size of 24 was calculated with a dropout rate of 10%.

Statistical analysis was performed using the IBM SPSS statistical software package (version 23.0). Sociodemographic data were analysed descriptively and presented as frequencies and percentages. All values were shown as mean ± standard deviation (SD) or median (range), and the number of patients (%) was used for all categorical data. Comparisons of variables between groups were performed by independent Student's t-test, a Mann-Whitney-U test, and a chi-square. A p-value of less than 0.05 was considered significant.

Results

A total of 24 patients were recruited for this study. They were allocated to the respective groups, and intervention was carried out according to the protocol. Figure 1 shows the consort flow diagram of the study. Demographic data are shown in Table 1. The weight was significantly higher in the deep group, but BMI was comparable between the two groups.

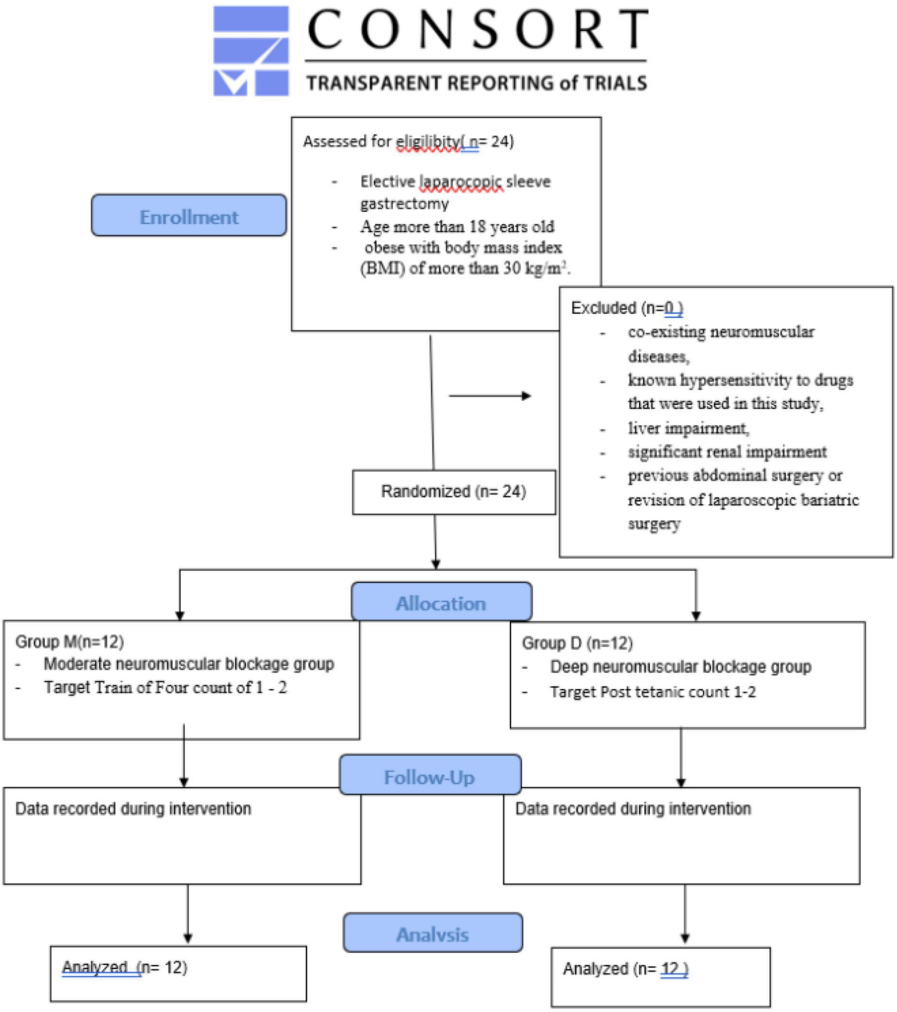

Fig. 1. Consort flow diagram.

Table 1. Demographic data

Variable	**Group M (n = 12)**	**Group D (n = 12)**	***p*-value**
Age (y)	40.5 (10.9)	40.8 (10.3)	0.945
Gender (male or female)	7:5	5:7	
Height (m)	1.65 (0.09)	1.60 (0.08)	0.164
Weight (kg)	123 (29)	101 (14)	0.027*
Body mass index (kg/m2)	45.1 (10.7)	39.6 (5.3)	0.125
Race			
Malay	9	8	
Chinese	1	0	
Indian	1	2	
Bidayuh	0	1	
Non-Malaysian	1	1	

All values are the mean (SD) or number of patients.
*Indicates statistical significance

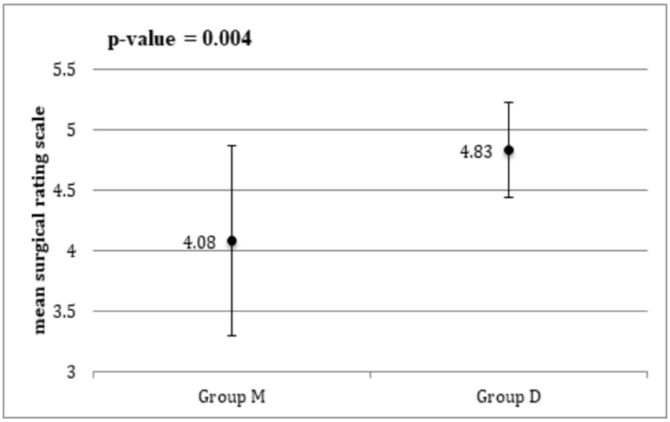

Fig. 2. Mean surgical rating scale obtained during the surgery A circle indicates the mean (SD).

Table 2 shows the hemodynamic parameters and the surgical data. Hemodynamic changes and intra-abdominal pressure measured during the procedure did not differ significantly between both groups. There was also no significant difference in the duration of surgery between both groups. The average duration of surgery was 157.0 minutes in Group M (range 105–210, median 157.5) and 178.8 minutes in Group D (range 135–250, median 167.5), with a p-value > 0.05. The mean dosage of opioids and anaesthetic agents was higher in Group M, as they were correlated to the weight of the patients seen in the demographic data. The mean dosage of sugammadex used was significantly higher in the moderate group. The mean SRS score was significantly higher in Group D (4.83 ± 0.39) compared with the score in Group M (4.08 ± 0.79) with a p-value = 0.004 as shown in Figure 2.

The distributions of all ratings taken during surgery are shown in Figure 3. In Group M, a score of 3 or less was observed in 8.3% of patients, and favourable conditions (SRS 4 and 5) were obtained in 91.7% (good 66.7% and optimal 25%), whereas in Group D all patients achieved good and optimal conditions (good 16.7% and optimal 83.3%). In terms of favourable conditions, more patients in Group D received optimal conditions (SRS 5) as compared with the moderate NMB. Figure 4 shows that 83.3% of patients in Group D and only 25% of patients in Group M obtained SRS 5 with a p-value = 0.004. Meanwhile, approximately 66.7% of patients in Group M and 16.7% in Group D achieved an SRS of 4 with a p-value = 0.013. The phi value for both SRS is more than 0.5, which indicates a strong association between the type of NMB and SRS.

Table 2. Measurements obtained during surgery

Variable	Group M	Group D	p-value
Mean blood pressure (mmHg)	83.0 (7.0)	84.0 (8.0)	0.748
Heart rate (min^{-1})	78.0 (10.0)	76.0 (12.0)	0.662
End-tidal CO_2 (mmHg)	40.0 (2.7)	39.5 (2.2)	0.624
Intraabdominal pressure	12.3 (0.6)	12.3 (0.5)	1.000
Duration of surgery (min)	157.0 (42.0)	178.8 (33.0)	0.171
Fentanyl (mcg)	152 (27)	130 (38)	0.058
Propofol (mg)	174 (34)	149 (35)	0.089
Total dose of rocuronium (mg)	93 (27)	103 (27)	0.374
Sugammadex (mg)	165 (25)	138 (21)	0.009*

All values were calculated as the mean (SD).
* Indicates statistical significance

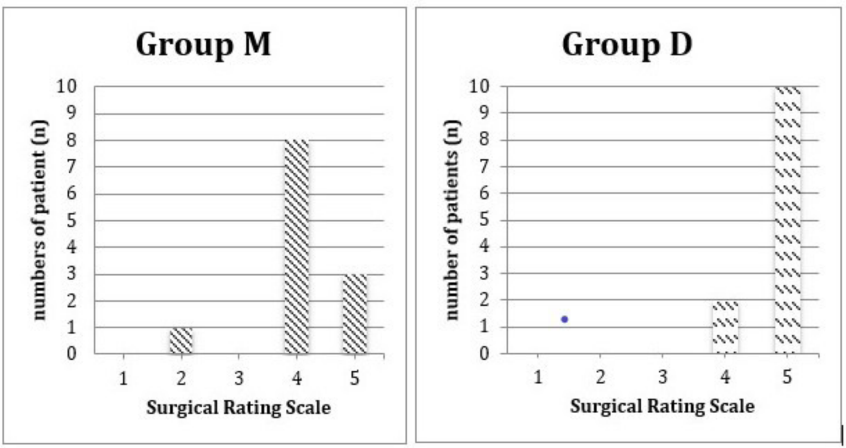

Fig. 3. Distribution of the Surgical Rating Scale (SRS) in moderate and deep blocks.

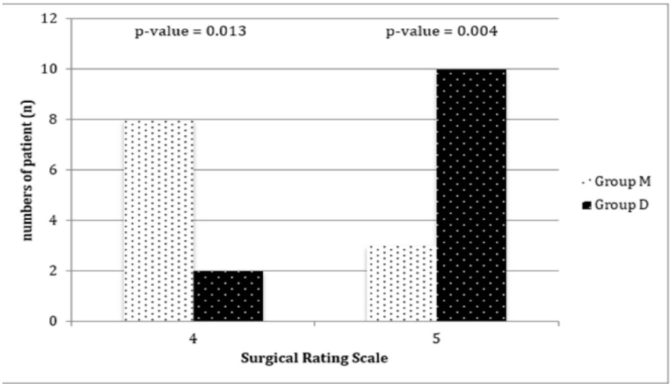

Fig. 4. Distribution of Surgical Rating Scale (SRS) of 4 and 5 in moderate and deep block.

Discussion

In this study, a deep NMB was associated with a higher rating score compared with the moderate NMB in laparoscopic sleeve gastrectomy. We observed that good and optimal conditions can be achieved during moderate NMB, although at a lower frequency (91.7%) than during deep NMB. The present findings align with prior observations in other surgical procedures, which have demonstrated that deep NMB consistently yields significantly higher SRS scores of 4 and 5 in diverse laparoscopic surgeries.[8,13] A meta-analysis also showed that excellent or good surgical conditions can be achieved by deep NMB in laparoscopic surgeries.[14] In our study, 8.3% of patients had unfavourable surgical conditions in the moderate NMB group and none in the deep block group.

The mean intra-abdominal pressure for both groups was 12.3 mmHg. Only one patient in the moderate NMB group required pressure up to 16 mmHg to achieve acceptable surgical space. Other investigators have used an intra-abdominal pressure of 13.2 mmHg for their laparoscopic bariatric surgery. Deep NMB has been shown to allow a lower intraabdominal pressure to be maintained during laparoscopic surgery.[15,16] The study period did not involve any adjustments to the intrabdominal pressure as long as the surgical conditions remained favourable. In a recent meta-analysis of randomised clinical trials, Yiyong *et al.* concluded that low intra-abdominal pressure with deep NBM was not significantly more effective than other intra-abdominal pressure and NMB combinations for optimising surgical space conditions.[17]

Our study found that the hemodynamic parameters were comparable between the two groups. First, we only included patients with no cardiac comorbidities in our population. Laparoscopic procedures can predispose to multiple cardiovascular complications as high intra-abdominal pressure results in increased afterload and a reduction in cardiac output.[18] Low intra-abdominal pressure may be beneficial for high-risk cardiac patients during laparoscopic surgery.[15]

The average duration of surgery in our study was similar between the two groups. This finding aligns with a meta-analysis conducted by Bruintjes *et al.*, which demonstrated a comparable duration of surgery among both groups of patients.[10] However, in a prospective observational study, Garneau *et al.* found that patients in the deep group had a significantly lower duration of surgery.[19]

To evaluate surgical conditions in our study, we used a 5-point SRS that has been validated in several studies.[5,6,13] Other scoring systems that have been used are the numerical rating scale (NRS) or the visual analogue scale (VAS) from 0 to 10. The NRS and VAS only reflect the quantitative aspects of the surgical condition. The scoring system should include the qualitative aspects that are important to surgeons when judging the surgical field. Thus, SRS was chosen due to its qualitative descriptions, which are integrated into the scoring system. To reduce variability, only one surgeon was involved in our study and evaluated the surgical conditions. He was able to discriminate between moderate and deep NMB and considered the changes in SRS to be clinically relevant.

Even though deep NMB has been proven to be beneficial, some anaesthesiologists might be reluctant to induce deep NMB during the entire procedure, especially in the obese population. The use of continuous muscle relaxants may result in hazardous effects such as residual paralysis postoperatively, especially in obese populations.[20] Despite the demonstrated improvement in SRS by surgeons, the clinical implications of deep NMB remain a subject of debate. Most meta-analyses have indicated that there is a comparable difference in surgical time and postoperative pain between the two groups.[9,10] Deep NMB also did not provide a superior surgical space compared to moderate NMB.[17]

The current use of sugammadex makes rapid reversal of deep NMB possible, alleviating concerns about postoperative complications. In our study, all patients were reversed with sugammadex. No respiratory complications were observed in either group in the postoperative anaesthesia care unit or in recovery. A retrospective study was conducted on a cohort of over 3,000 cancer patients who underwent laparoscopic stomach surgery. The findings revealed that patients in the sugammadex group exhibited significantly reduced complications and length of hospital stay as compared to those in the neostigmine group.[21]

The main limitation of our study was its small sample size. We also only assessed the SRS and did not assess other benefits of deep NMB after the procedure. Apart from that, respiratory function, return to routine physical activities, and length of hospital stay were not documented.

Conclusions

A deep NMB provided favourable surgical conditions compared with a moderate NMB in the laparoscopic sleeve gastrectomy. However, there was no difference in terms of haemodynamic parameters, duration of surgery, or intra-abdominal pressure between the groups.

Declarations

Ethics approval and consent to participate

The study was conducted in accordance with the Declaration of Helsinki and approved by the Medical Research and Ethics Committee of Universiti Kebangsaan Malaysia Medical Centre (FF-2015-361). Patients scheduled for the surgery were recruited, and written informed consent was obtained.

Competing interests

Dr Azarinah Izaham serves as Section Editor in Malaysian Journal of Anaesthesiology. She has not been involved in any part of the publication process prior to manuscript acceptance; peer review for this journal is double blind. The remaining authors have no competing interests to declare.

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Appendix 1

Measurement of ideal body weight (IBW), lean body weight (LBW), and corrected body weight (CBW) (18–21)

Ideal body weight calculation

IBW (kg) = height (cm) – x

IBW: ideal body weight

x = 100 for adult males and 105 for adult females.

Lean body weight calculation

LBW (kg) for male = (1.10 x BW) - (0.0128 x BMI x BW)

LBW (kg) for female = (1.07 x BW) - (0.0148 x BMI x BW)

LBW: lean body weight

BW: body weight (total)

BMI: body mass index (kg/m^2)

Corrected body weight calculation

CBW = IBW + (0.4 x excess weight)

CBW (corrected body weight)

IBW: ideal body weight

Appendix 2

Table 1. Surgical Rating Scale (SRS)

SRS	Descriptions
1	Extremely poor condition Unable to work Coughing or inability to obtain a visible field because of inadequate muscle relaxation
2	Poor condition Visible laparoscopic field Surgeon is severely hampered by inadequate muscle relaxation with continuous muscle contractions, movements, or both
3	Acceptable condition Wide visible field Muscle contractions, movements, or both occur regularly
4	Good condition Wide visible field Sporadic muscle contractions or movements, or both
5	Optimal condition Wide visible working field No muscle movement or contraction