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Effect of neuromuscular block on surgical conditions during short-duration paediatric laparoscopic surgery involving a supraglottic airway

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Abstract

Background: Use of an LMA ProSeal™ laryngeal mask airway (P-LMA; Teleflex) with no neuromuscular block is considered a safe alternative to tracheal intubation in short-duration paediatric laparoscopic surgery. However, few studies have evaluated surgical conditions of short-duration paediatric laparoscopic surgery using this anaesthetic technique. We assessed surgical conditions for paediatric laparoscopic inguinal hernia repair using P-LMA with and without neuromuscular block.

Methods: Sixty-six patients undergoing laparoscopic inguinal hernia repair were randomised to receive a neuromuscular block (train-of-four 1–2 twitches) using rocuronium or no neuromuscular block with the P-LMA. All operations were performed by the same surgeon who determined the surgical conditions using the Leiden-surgical rating scale (L-SRS). Secondary outcomes included perioperative data, haemodynamics, and adverse events.

Results: Neuromuscular block improved surgical conditions compared with no neuromuscular block: mean (standard deviation) L-SRS 4.1 (0.5) *vs* 3.5 (0.6), respectively ($P<0.0001$). Mean rocuronium dose in the neuromuscular block group was 12.7 (4.4–29.7) mg or 0.7 (0.6–0.8) mg kg^{-1}. The insufflation Ppeak was higher in the no neuromuscular block group than in the neuromuscular block group: mean (standard deviation) Ppeak 17.9 (1.8) cm H_2O *vs* 16.2 (1.9) cm H_2O, respectively ($P=0.0004$). Fifteen children (45.5%) in the no neuromuscular block group had adverse events during the surgery and anaesthesia *vs* four children (12.1%) in the neuromuscular block group ($P=0.006$).

Conclusions: Neuromuscular block significantly improved surgical conditions and reduced the incidence of adverse events during surgery and anaesthesia when an LMA Proseal™ was used in short-duration paediatric laparoscopic surgery.

Clinical trial registration: ChiCTR2000038529.

Keywords: laparoscopy; laryngeal mask airway; neuromuscular block; paediatric; sugammadex; surgical conditions

Editor's key points

- Few studies have evaluated the surgical conditions of short-duration paediatric laparoscopic surgery using a supraglottic airway without neuromuscular block.
- The authors assessed surgical conditions for paediatric laparoscopic inguinal hernia repair using the LMA ProSeal™ laryngeal mask airway with and without neuromuscular block.
- Neuromuscular block significantly improved surgical conditions when an LMA Proseal™ was used in short-duration paediatric laparoscopic surgery.

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Although general anaesthesia with tracheal intubation is generally preferred for paediatric laparoscopic surgery, laryngeal mask airways (LMAs) are safe and widely used for securing the airway in short-duration paediatric laparoscopic surgery.[1–3] Laparoscopic repair of inguinal hernias is one example of a short-duration laparoscopic surgery performed in children. Advances in surgical techniques have significantly reduced the operative time of laparoscopic repair for inguinal hernia in children.[4–6] The need for neuromuscular blocking agents in this procedure is controversial. Some studies have suggested that neuromuscular block is unnecessary when an LMA ProSeal (P-LMA) or Supreme LMA is used during laparoscopic repair for inguinal hernia in children.[7,8] However, neuromuscular block is known to improve operating conditions for laparoscopic surgery.[9–11] There are few studies on the effect of neuromuscular block on the surgical conditions of short-duration laparoscopic surgery in children.

We assessed the surgical conditions during laparoscopic repair for inguinal hernia in children using the P-LMA with and without neuromuscular block. This study was designed to test the hypothesis that neuromuscular block is associated with higher surgical ratings compared with no neuromuscular block during paediatric laparoscopic inguinal hernia repair, and to compare perioperative data, haemodynamics, and adverse events.

Methods

This was a single-centre RCT approved by the China Ethics Committee for Registering Clinical Trials (ethical committee file number: ChiECRCT20200260, approved on September 9, 2020). The study was registered at the Chinese Clinical Trial Registry (ChiCTR2000038529) and was performed between September 2020 and December 2020 at Hunan Children's Hospital (Hunan, China).

Potential participants were identified from the elective surgery list by a research team member who approached the family before surgery to determine eligibility for the study. Parents/guardians were told verbally and in writing of the details of the study and the possible consequences. All parents/guardians gave written informed consent for participation of their children in this study, and assent from the patient was sought when applicable. The research assistant and the surgeon who scored the surgical conditions were both blinded to the treatment, whereas the attending anaesthetist was not. The patients were randomised into two groups using a code generated by a computer: the no neuromuscular block group and the neuromuscular block group. The codes of the enrolled patients were sealed in an airtight envelope and presented to the attending anaesthetist.

Patients aged 0–12 yr, weighing <40 kg and scheduled to undergo laparoscopic repair of a unilateral (left or right) inguinal hernia were recruited. All operations were performed by the same surgeon. Patients with repeat hernia repair on the same side, ASA physical status >3, known or suspected neuromuscular disease, bronchial asthma, allergy to medication to be used during anaesthesia, severe obesity (BMI $\geq$25 kg m^{-2}), congenital heart disease, congenital airway malformation, or a high risk of perioperative respiratory adverse events (including a cold within the previous 2 weeks, wheezing within the past 12 months, wheezing while exercising, nocturnal dry cough, past/present eczema, passive smoking, and a family history of hay fever/asthma/eczema)[12] were excluded from the study.

Anaesthesia protocol and groups

All enrolled subjects received TIVA with propofol and sufentanil induced with sufentanil 0.2–0.5 μg kg^{-1} and propofol 2–5 mg kg^{-1}. A P-LMA (LMA ProSeal™, Teleflex, Limerick, PA, USA) was used for securing the airway according to the manufacturer's instructions. After P-LMA placement, bilateral pulmonary auscultation was performed to confirm ventilation. When gas leakage was detected, the P-LMA was adjusted by the attending anaesthesiologist. Subjects with a leak after two relocations of the P-LMA underwent tracheal intubation and were excluded from the study. Propofol was used to maintain anaesthesia, and bispectral index (BIS) was maintained between 40 and 50. A train-of-four (TOF) watch (TOF-watch SX, MSD BV, Oss, the Netherlands) was calibrated before performing the neuromuscular block. Neuromuscular monitoring was standardised: (1) tetanic ulnar nerve stimulation was applied; (2) TOF watch was calibrated; and (3) three TOF measurements were performed to ensure that the TOF ratio differed by <5% between measurements. If these three measurements differed by >5%, the TOF watch was recalibrated. After these steps, the neuromuscular blocking agent was administered according to the treatment protocols of the groups as follows.

Neuromuscular block group: rocuronium 0.5 mg kg^{-1} i.v. followed by continuous infusion of rocuronium to maintain TOF count at 1–2 twitches. The infusion speed was adjusted or a bolus dose was given for deviations from the target TOF values.

No neuromuscular block group: subjects in this group were given an identical volume of saline placebo.

After neuromuscular block reached the target depth (TOF count 1–2 twitches), CO_2 insufflation was initiated to 8 cm H_2O. Tidal volume was set to 10 ml kg^{-1}, gas flow was set to 2 L min^{-1}, and ventilatory frequency set according to the child's age. During the operation, ventilatory frequency was adjusted according to $EtCO_2$. When poor or extremely poor surgical conditions occurred, rocuronium 0.5 or 0.3 mg kg^{-1} were administered in the no neuromuscular block and neuromuscular block groups, respectively. At the end of surgery, a single bolus of sugammadex 2 mg kg^{-1} i.v. was administered to reverse moderate neuromuscular block (TOF 1–2 twitches) in the neuromuscular block group. Spontaneous respiration was obtained by decreasing the infusion speed of the propofol, and the P-LMA was removed in the no neuromuscular block group. In the neuromuscular block group, the P-LMA was removed when the TOF ratio was >0.9. During recovery, the ratio of the fourth to the first twitch is the TOF ratio.

Monitoring

All subjects underwent routine monitoring using electrocardiography, pulse oximetry, noninvasive blood pressure, heart rate, depth of anaesthesia (BIS), and capnography during the procedure. Depth of the neuromuscular block was monitored by measuring the TOF count, which was measured every 5 min.

Surgical rating scale

During pneumoperitoneum, the surgeon evaluated conditions every 5 min according to the Leiden-surgical rating scale (L-SRS).[13] The L-SRS quantifies surgical operation conditions in terms of visibility, surgical space, muscle contractions, handling tactics, and patient movement as follows: extremely poor (score 1) indicates that the surgeon was unable to perform

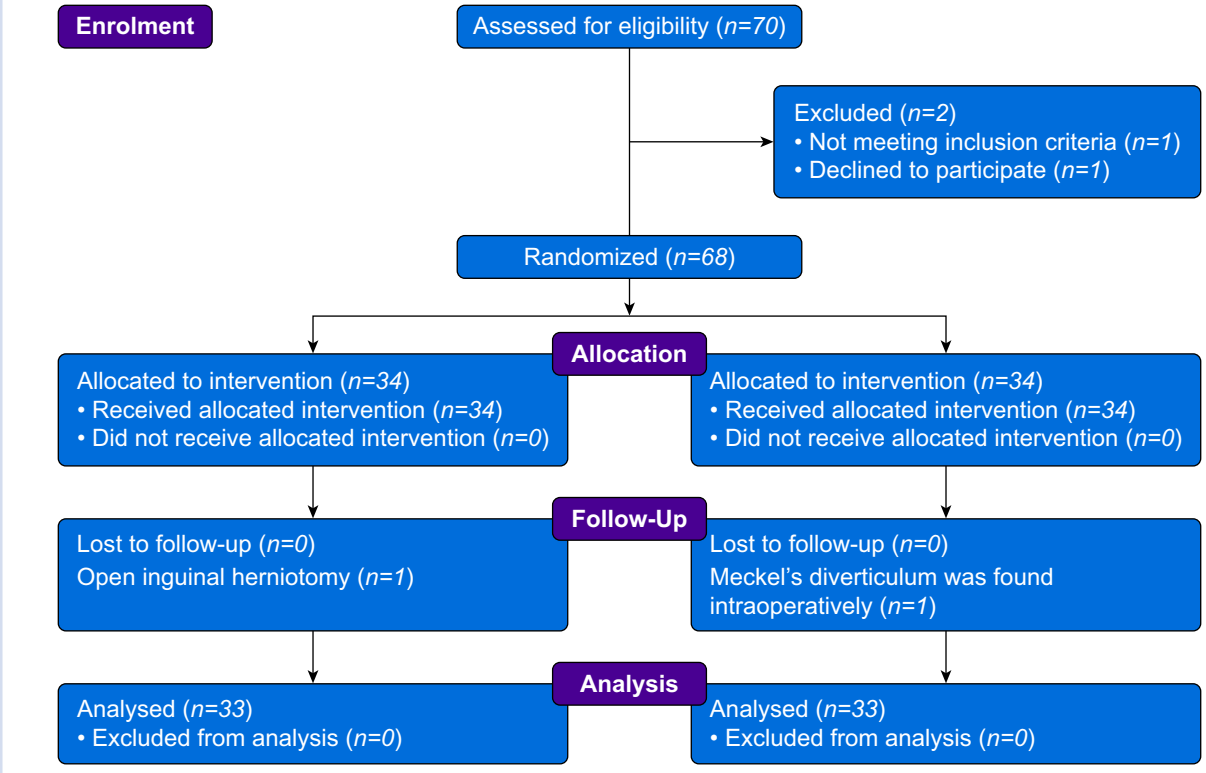

Fig 1. Study flowchart.

the operation because of coughing or an inability to obtain a visible field because of inadequate muscle relaxation; poor (score 2) indicates that there was a visible field but that the surgeon was severely hampered by inadequate muscle relaxation as indicated by continuous muscle contractions, movements, or both; acceptable (score 3) indicates that despite the presence of a wide, visible field, muscle contractions, movements, or both occurred regularly; good (score 4) indicates a wide working field with sporadic muscle contractions, movements, or both; and excellent (score 5) indicates a wide visible working field without any movements or contractions.

Outcome measures

The primary outcome measure was the mean L-SRS, evaluated every 5 min during pneumoperitoneum by the surgeon who was blind to the treatment group. The secondary outcome measures included Ppeak, blood pressure, heart rate, surgery time, anaesthesia time, laryngeal mask removal time, PACU discharge time, and perioperative adverse events. Perioperative adverse events, including laryngospasm, bronchospasm, apnoea, hypoxaemia, Ppeak during insufflation $\geq$20 cm H_2O, intraoperative movement, aspiration, and P-LMA repositioning, were recorded in the operating room or PACU. The L-SRS scores were recorded by a research assistant. Secondary outcome data were recorded by the attending anaesthetist and the PACU anaesthesiology nurse.

Outcome measures were defined as surgical time (time from the beginning of skin preparation to the completion of surgery wound dressing), anaesthesia time (time from induction to removal of the airway device), laryngeal mask removal time (time from cessation of propofol administration to removal of the P-LMA), PACU discharge time (time from PACU admission until a modified Aldrete scale score $\geq$9 was achieved), laryngospasm (defined as complete airway obstruction with associated muscle rigidity of the abdominal and chest walls), bronchospasm (defined as increased respiratory effort, particularly during expiration, and wheezing on auscultation), and apnoea (defined as a pause in breathing lasting >15 s or a pause in breathing of any duration leading to SpO_2 <80% or bradycardia).

Sample size and statistical analysis

Preliminary data showed the mean and standard deviation of L-SRS for patients without neuromuscular block were 3.67 and 0.53, respectively. We calculated that a minimum of 24 subjects would be required for each group to show a 0.5-point difference in L-SRS (α=0.05 and β=0.1). Therefore, we planned to enrol a total of 70 subjects to account for potential protocol omissions. Continuous study variables are summarised as mean (standard deviation) according to study group and were compared using a two-sample *t*-test. Categorical variables are summarised as frequencies and percentages and were analysed using Fisher's exact test. We performed additional analyses including unitary linear regression analysis of age and L-SRS and a comparison of L-SRS in children aged 0–3 yr between groups. *P*-values <0.05 were considered statistically significant. All analyses were performed using IBM SPSS Statistics 26.0 (SPSS Inc., Chicago, IL, USA).

Results

A total of 70 patients were screened. One patient met the exclusion criteria, and one patient declined to participate. The others were randomised and received treatment with or without rocuronium (Fig. 1). The subject characteristics in each group are given in Table 1, showing no significant differences between groups.

Rating of surgical conditions during laparoscopic surgery

Mean surgical condition scores were 3.5 (0.6) (range 2.3–4.5, median 3.5) in the no neuromuscular block group, and 4.1 (0.5) (range 3.0–5.0, median 4.0) in the neuromuscular block group (Fig. 2). The surgical field scores were significantly different between groups ($P<0.0001$).

Perioperative measurements

The BIS, haemodynamic variables, basal Ppeak, surgery time, anaesthesia time, laryngeal mask removal time, and PACU discharge time were similar between groups (Table 2). The median (range) of TOF count in the neuromuscular block group was 1 (1–3) during surgery, and the mean dose of rocuronium was 12.7 (4.4–29.7) mg or 0.7 (0.6–0.8) mg kg^{-1}. The no neuromuscular block group had a higher average Ppeak during insufflation with a value of 17.9 (1.8) *vs* 16.2 (1.9) cm H_2O for the neuromuscular block group ($P=0.0004$).

Perioperative adverse events

Fifteen children (45.5%) in the no neuromuscular block group and four children (12.1%) in the neuromuscular block group experienced adverse events during anaesthesia and surgery (Table 3; $P=0.006$). There was no difference in the incidence of adverse events in the PACU between groups.

Post hoc analysis of the relationship between age and surgical condition

There was a correlation between age and the surgical condition scores ($r^2=0.531$, $P<0.0001$; Fig. 3a) in the no neuromuscular block group but not in the neuromuscular block group ($r^2=0.020$, $P=0.430$; Fig. 3a). There was no significant difference in the surgical condition scores of children aged 0–3 yr between groups: mean rating 4.1 (0.4) (range 3.5–4.7, median 4.2) for the neuromuscular block group and 4.0 (0.4) (range 3.3–4.5, median 4.0) for the no neuromuscular block group ($P=0.476$; Fig. 3b).

Table 1 Subject characteristics and screening measurements. All values denote mean (standard deviation) unless otherwise stated.

	No neuromuscular block ($n=33$)	Neuromuscular block ($n=33$)
Sex (M/F)	25/8	26/7
Median age, yr (range)	3.8 (0.6–11.5)	4.2 (0.5–11.7)
Age group, *n* (%)		
0–3 yr	14 (42%)	12 (36%)
3.1–6 yr	9 (27%)	10 (30%)
6.1–9 yr	6 (18%)	7 (21%)
9.1–12 yr	4 (12%)	4 (12%)
Weight (kg)	18.0 (8.3)	18.5 (8.8)
Height (cm)	106.4 (22.1)	107.5 (23.8)
BMI (kg m^{-2})	15.1 (1.9)	15.2 (1.4)
ASA physical status (1/2)	30/3	31/2

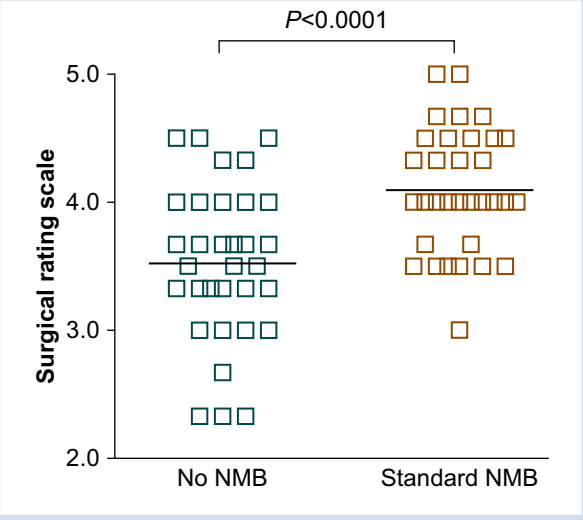

Fig 2. Surgical ratings by the surgeon during laparoscopic surgery using the 5-point surgeon rating scale (SRS). The surgical ratings obtained during neuromuscular block (NMB) were significantly higher than those obtained during no neuromuscular block ($P<0.0001$).

Discussion

We assessed surgical working conditions during short-duration paediatric laparoscopic surgery using P-LMA with and without neuromuscular block. Neuromuscular block significantly improved surgical conditions over no neuromuscular block during short-duration paediatric laparoscopic surgery. Moreover, neuromuscular block reduced the incidence of adverse events during surgery and anaesthesia in short-duration paediatric laparoscopic surgery.

Our results show that neuromuscular block increased surgical condition scores for laparoscopic inguinal hernia repair in children by more than 0.5 points compared with no neuromuscular block. A difference of >0.5 points in the L-SRS score is considered clinically significant.[12] Administration of neuromuscular blockers is essential for a variety of procedures, as it causes a decrease in unacceptable surgical conditions and unnecessary surgical complications.[14,15] However, many anaesthesiologists have expressed concern about the prolonged recovery time and incomplete recovery of neuromuscular function associated with neuromuscular block and therefore use no or shallow neuromuscular block in paediatric laparoscopic inguinal hernia repair. Although no serious surgical complications occurred in the no neuromuscular block group in our study, the surgeon indicated that more effort was needed to introduce the trocars when the patient did not receive a neuromuscular blocker. This was not reflected in our data, but this additional effort may increase the chance of a trocar damaging internal organs. In addition, the combination

Table 2 Perioperative data expressed as mean (standard deviation) unless otherwise stated. Ppeak, peak airway pressure; TOF, train-of-four.

	No neuromuscular block (n=33)	Neuromuscular block (n=33)	P-value
Arterial blood pressure, systolic (mm Hg)	93.2 (9.9)	92.0 (11.9)	0.654
Arterial blood pressure, diastolic (mm Hg)	51.7 (9.8)	50.4 (10.4)	0.620
Bispectral index	44 (3)	45 (3)	0.139
Heart rate (min^{-1})	105 (12)	103 (13)	0.451
Basal Ppeak (cm H_2O)	13.4 (1.8)	13.1 (1.5)	0.374
Ppeak during insufflation (cm H_2O)	17.9 (1.8)	16.2 (1.9)	0.0004
Surgery time (min)	15.9 (4.5)	15.2 (3.9)	0.485
Anaesthesia time (min)	30.5 (5.7)	29.9 (5.1)	0.649
Laryngeal mask removal time (min)	3.3 (1.7)	3.8 (1.7)	0.279
PACU discharge time (min)	11.1 (2.0)	11.7 (1.5)	0.174
TOF count, median (rang)	–	1 (1–3)	–
Rocuronium, mean (range), (mg)	–	12.7 (4.4–29.7)	–
Rocuronium, mean (range), (mg kg^{-1})	–	0.7 (0.6–0.8)	–

of rocuronium and sugammadex did not prolong the duration of anaesthesia, recovery, or surgery, instead guaranteeing rapid recovery and patient turnover from short-duration paediatric surgery in our study. In conclusion, neuromuscular block can improve surgical conditions for short-duration laparoscopic surgery in children when using a P-LMA.

Most studies have shown that deep neuromuscular block improves surgical conditions compared with moderate or no neuromuscular block.[9,11,16,17] However, Honing and colleagues[18] found that during sevoflurane anaesthesia, deep neuromuscular block did not improve surgical conditions over moderate block in normal-pressure laparoscopic renal surgery. The reason may be that, unlike intravenous anaesthetics such as propofol, volatile anaesthetics augment muscle relaxation.[19,20] Therefore, deep neuromuscular block has no significant advantage over moderate neuromuscular block in optimising surgical conditions when sevoflurane anaesthesia is used. In our study, we opted for TIVA to avoid false-positive results caused by the enhancement of neuromuscular block by volatile anaesthetics.

The neuromuscular block group had a lower incidence of anaesthesia- and surgery-related adverse events relative to the no neuromuscular block group. Airway pressure during insufflation in the neuromuscular block group was lower than that in the no neuromuscular block group. The risk of perioperative adverse respiratory events has been shown to be significantly lower when intubation was performed with neuromuscular block than without.[21] A meta-analysis showed that the incidence of laryngospasm is lower when controlled ventilation using neuromuscular block is used in tracheobronchial foreign body removal.[22] Moreover, there was less intraoperative movement in the neuromuscular block group. Notably, two

Table 3 Perioperative adverse events expressed as percentage (%). LMA, laryngeal mask airway; P-LMA, LMA ProSeal™; Ppeak, peak airway pressure.

Adverse events	No neuromuscular block (n=33)	Neuromuscular block (n=33)	P-value
Operating room (period of surgery and anaesthesia)	n (%)	n (%)	
Laryngospasm/bronchospasm	4 (12.1)	1 (3.0)	0.355
Apnoea	0 (0)	0 (0)	–
Hypoxaemia	1 (3.0)	1 (3.0)	1.000
Ppeak during insufflation ≥20 cm H_2O	7 (21.2)	2 (6.1)	0.149
Aspiration	0 (0)	0 (0)	–
P-LMA reposition	4 (12.1)	1 (3.0)	0.355
Intraoperative movement	4 (12.1)	1 (3.0)	0.355
Incision	1 (3.0)	0 (0)	–
Introduce trocar	2 (6.1)	0 (0)	–
Intraperitoneal operation	0 (0)	0 (0)	–
Skin sutures	1 (3.0)	1 (3.0)	–
Any adverse events	15 (45.5)	4 (12.1)	0.006
PACU			
Laryngospasm/bronchospasm	0 (0)	0 (0)	–
Apnoea	2 (6.1)	3 (9.1)	1.000
Hypoxaemia	3 (9.1)	5 (15.2)	0.709
Any adverse events	4 (12.1)	6 (18.2)	0.733

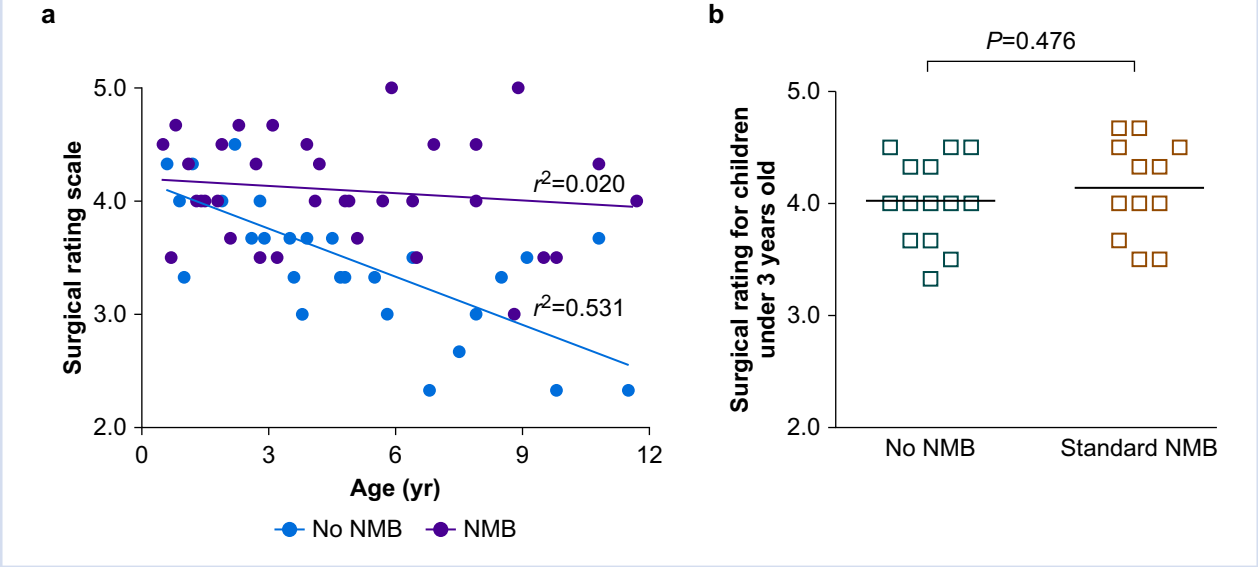

Fig 3. *Post hoc* analysis. (a) Linear regression between age and surgical ratings. In the no neuromuscular block (NMB) group, there was a negative correlation between age and surgical ratings (r^2=0.531). In the neuromuscular block group, there was no correlation between age and surgical ratings (r^2=0.020). (b) Surgical ratings for children younger than 3 yr during laparoscopic surgery. There was no significant difference between the no neuromuscular block group and the neuromuscular block group (P=0.476).

patients in the no neuromuscular block group moved during trocar placement. Although no additional serious complications occurred for these patients, movement increases the chance of visceral injury. Although our data show a statistically significant difference in adverse events between the neuromuscular block group and the no neuromuscular block group, the small sample size was small and the number of events low such that these results may not be reproducible. Based on the incidence of adverse events in the no neuromuscular block group of 45.5%, we calculate that a minimum of 86 subjects in each group would be required to show a 20% difference in the rate of adverse events (α=0.05 and β=0.2). Hence, a larger sample size is needed to determine the advantage of neuromuscular block in terms of adverse events.

The incidence of respiratory adverse events during the PACU stay was similar in the two groups. Although both groups of patients developed hypoxaemia, these transient events were easily managed with gentle stimulation, oxygen supplementation, and bag-mask ventilation. No residual neuromuscular block or signs or symptoms of critical respiratory events occurred in the neuromuscular block group while in the PACU. However, Hammer and colleagues[23] found that use of neuromuscular blocking agents in patients managed with a supraglottic airway (SGA) device or tracheal tube was associated with a slightly higher risk of emergent postoperative intubation and a higher risk of immediate postoperative hypoxaemia. It is important to note that their study subjects were adults and that use of opioid analgesics, succinylcholine, or reversal agents did not affect the findings. In our study, the incidence of hypoxaemia during PACU stay was increased in the neuromuscular block group compared with the no neuromuscular block group (15.2% *vs* 9.1%). This finding is similar to the results of Hammer and colleagues[23] and may be relevant to the use of neuromuscular block, although not statistically significant. Similarly, Hunter and Aziz[24] suggested caution when using an SGA device with neuromuscular block. In our study, the incidence of respiratory adverse events in the PACU was not significantly different between the two groups, which may be attributable to the small size of our study.

In our *post hoc* analysis of the data, unitary linear regression analysis showed that surgical condition scores were negatively correlated with age in the no neuromuscular block group, but not in the neuromuscular block group. Parke and colleagues[25] showed that muscle strength increases with age and that children younger than 12 yr show similar trends in muscle strength development. Therefore, we speculated that increased muscle strength in children might influence surgical conditions for laparoscopic surgery when no neuromuscular block is used. We also found no significant difference between the two groups in surgical rating scores. When using a P-LMA, use of neuromuscular block had little impact on surgical conditions for children younger than 3 yr undergoing short-duration laparoscopic surgery.

There are several limitations to our study. First, although the sample size is sufficient for the primary endpoint, it was too small for the secondary outcomes concerning adverse events. Second, we did not record postoperative adverse events. Anaesthesia- or surgery-related adverse events may also occur after leaving the PACU, and we do not have data for that period. Third, the attending anaesthetist was not blinded to the grouping of the study. This may have led to bias despite the objectivity and clear definitions of our assessment outcomes, such as surgery time, airway peak pressure, and the incidence of adverse events. Finally, we showed that neuromuscular block necessary for surgical optimisation does not

necessarily require tracheal intubation of the patient, but the safety aspect of this procedure needs to be further studied.

In conclusion, moderate neuromuscular block significantly improved surgical conditions and reduced adverse events during anaesthesia and surgery in short-duration paediatric laparoscopic surgery using a P-LMA compared with no neuromuscular block. Rocuronium in combination with sugammadex did not prolong recovery time or cause residual neuromuscular block. Neuromuscular block is necessary for short-duration laparoscopic surgery in children.

Authors' contributions

Study design/planning: LW, SQQ.
Study conduct: LW, SWW, ZX, EYY.
Data analysis and writing of the manuscript: LW.
Revision of the manuscript: LW, SQQ, ZD.

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Declarations of interest

The authors declare that they have no conflicts of interest.

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