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Prospective Clinical Trial

Short-lasting pediatric laparoscopic surgery: Are muscle relaxants necessary? Endotracheal intubation vs. laryngeal mask airway

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ABSTRACT

Purpose: Technical advances have led to lower insufflation pressures and shorter anesthesia times for children undergoing laparoscopic procedures. In this study we compared the use of endotracheal tube (ETT) and laryngeal mask airway (LMA) with or without muscle relaxant (MR) in children undergoing laparoscopic repair for inguinal hernia.
Methods: Children undergoing laparoscopic inguinal hernia repair were randomized into four groups which underwent procedure with either ETT + MR (group 1), ETT without MR (group 2), LMA with subparalytic dose of MR (group 3) or LMA without MR (group 4). Surgical, anesthesia and recovery times, intragastric pressures and peak airway pressures during insufflation were compared.
Results: After exclusion criteria and discontinued interventions, groups 1 and 3 contained 20, groups 2 and 4 contained 19 patients each. Surgical times were similar between groups. Anesthesia times were statistically significantly different between groups with shortest time in group 4 and longest time in group 1. Recovery time was statistically significantly longer in group 1 when compared to other groups. There was no difference between basal intragastric pressure, average intragastric pressure during insufflation, peak airway pressure, and average peak airway pressure during insufflation of groups.
Conclusion: Use of muscle relaxants in short-lasting laparoscopic procedures in children is not absolutely necessary and LMA with subparalytic dose of muscle relaxant or with no muscle relaxant is a safe alternative.
Type of study: Treatment study.
Level of evidence: Level II.

Inguinal hernia is one of the most frequent indications for surgery in children, and its minimal invasive repair has recently gained popularity [1–4]. Inguinal hernia repair is performed under general anesthesia. While both endotracheal intubation (ETT) and laryngeal mask airway (LMA) devices can be used as airway management devices during conventional pediatric inguinal hernia repair, ETT is generally preferred when laparoscopic hernia repair is performed. Although there are reports in literature of the safe use of laryngeal mask airway (LMA) in pediatric laparoscopic surgery [5–7], its use has not gained popularity [8].

For more than 30 years, Laryngeal Mask Airway-Classic™ (C-LMA) has been used in adults and children for short-lasting surgical procedures where the patient is in the supine position. New LMA models have been developed and their use has been increasing [5,9]. Developed in 2000, LMA-Proseal™ (P-LMA) also provides gastric access while LMA is in situ [10,11]. However, ETT is still the gold standard, especially in patients who have a high risk of aspiration of gastric contents, such as those with a full stomach or with gastric motility problems [12].

Recently, more minimally invasive laparoscopic techniques for the repair of pediatric inguinal hernia with surgical times of 15–20 min have been reported [2,4]. Low insufflation pressures and shorter anesthesia times have led to a review of the need for ETT and muscle relaxants in these patients.

This study aimed to answer two research questions: a) can P-LMA be safely used in short-lasting pediatric laparoscopic surgery; b) is the use of muscle relaxants absolutely necessary in these procedures? In order to answer these questions, we compared the use of ETT and P-LMA with or without muscle relaxants in patients undergoing laparoscopic repair for inguinal hernia. Comparison was performed by analyzing surgical times, anesthesia times and pressure variables, with the null hypothesis that there was no difference between combinations.

1. Material & methods

This blinded, prospective, randomized safety control study was performed after local ethics committee approval and in accordance with

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the principles outlined in the Declaration of Helsinki. The study was registered with clinicaltrials.gov (Registration No: NCT02696837) and CONSORT checklist was used for enrollment and allocation of patients. (Fig. 1) Recruitment was performed between March 2016 and May 2016 and surgical procedures took place between March 2016 and June 2016. All parents gave written informed consent for participation of their children in this study.

Patients aged between 0 and 12 years and <30 kg who were due to undergo laparoscopic repair for single-sided inguinal hernia or communicating hydrocele were recruited. Those with previous abdominal surgery and/or comorbidities that would affect surgical time, time under anesthesia, intragastric pressure (IGP) and abdominal pressure were excluded from the study.

1.1. Anesthesia technique & groups

Using the closed envelope method, patients were randomized into four possible groups on the morning of surgery. Closed envelope was chosen by a ward nurse. The randomization process and its records were conducted under the supervision of a single author (DTT). Each group consisted of 20 patients. All patients received 0.5 mg/kg of oral midazolam 1 h before surgery. In the operating room, IV access was inserted, patients were routinely monitored and preoxygenation was administered.

Group 1:
In this group, patients underwent ETT with a muscle relaxant. First, 0.5-mg/kg lidocaine (Aritmal %2, Osel Ilaç, Turkey) was intravenously administered. Subsequently, 1-mcg/kg fentanyl (Talinat 0.1 mg/2 mL, VEM İlaç, Turkey), 2.5-mg/kg propofol (Pofol IV ampul 10 mg/mL, Sandoz Ilaç, Turkey) was administered. Lastly, 0.6-mg/kg rocuronium (Esmeron 10 mg/mL, Merck Sharp Dohme İlaç, Turkey) was administered and ETT intubation performed.
Group 2:
In this group, patients underwent ETT without a muscle relaxant. After 0.5 mg/kg of lidocaine, remifentanil (Ultiva 2 mg, Glaxosmithkline İlaç, Turkey) 2 μg/kg (bolus in 30–60 s) and 2.5-mg/kg propofol were administered. After depth of anesthesia was achieved, ETT intubation was performed.
Group 3:
In this group, patients underwent surgery with P-LMA using a subparalytic dose of nondepolarizing muscle relaxant. Following 0.5-mg/kg lidocaine, 1-mcg/kg fentanyl, 2.5-mg/kg propofol and 0.2-mg/kg rocuronium was respectively administered and appropriate P-LMA according to age and weight was placed.
Group 4:
In this group, patients underwent surgery with P-LMA with no muscle relaxant. Following 0.5-mg/kg lidocaine, 1-mcg/kg fentanyl and 2.5-mg/kg propofol were administered and appropriate P-LMA according to age and weight was placed.

Anesthesia was maintained using inhalation of 2% sevoflurane. Ventilation parameters were set as tidal volume of 10 ml/kg and respiratory rate of 15 per minute. Respiratory rate was adjusted perioperatively according to the patients' EtCO2. Fresh gas flow was set at 3 lt/m. In groups 1 and 3 where muscle relaxants were used, the effect of muscle relaxant was reversed using atropine 0.02 mg/kg and neostigmine 0.04 mg/kg that was administered when patients were observed to swallow.

ETT was chosen using the formula age/4 + 4.5. All ETT were uncuffed. P-LMA was chosen according to reference written on the products manual. Following ETT or P-LMA placement, bilateral lung auscultation was performed and ventilation was confirmed using a capnograph. Epigastric auscultation was performed to determine air leakage. When air leakage was detected, P-LMA was reintroduced. Patients with air leakage following two placements were intubated and excluded from the study. For patients with air leakage after ETT, patients were re-intubated using a 0.5 larger size tube. Patients who had air leakage after second intubation and patients with 2 or more failed intubation attempts were excluded from the study as peri and postoperative outcome measures may be effected.

1.2. Patient monitoring

All patients underwent monitoring using electrocardiography, pulse oximetry, non-invasive blood pressure monitoring, capnography and EtCO2. Following induction, 8–14-Fr tube was placed orogastrically. Gastric content and air were aspirated and the orogastric tube was removed. P-LMA or ETT was placed immediately after this aspiration. Following intubation or P-LMA placement, a 8–14-Fr tube was attached to the pressure transducer using a three way stopcock. The nasogastric tube was filled with sterile saline and pressure transducer was zeroed. The nasogastric tube was lubricated and in groups 1 and 2 placed orogastrically and in groups 3 and 4 placed through the P-LMA's drainage port. Pressure measurements were made using the anterior axillary line at the level of the xiphoid process as a reference point. Pressure measurements were made using the hydrostatic pressure measurement technique reported previously [5].

1.3. Surgical technique

Inguinal hernia repair was performed in the supine position, using the PIRS (percutaneous internal ring suturing) technique in all patients, as previously described [2]. Insufflation pressure was set at 8 cmH2O for all patients.

1.4. Intraoperative measurements

Following skin preparation and sterile draping of patient, EtCO2, IGP, insufflation pressure, SpO2, HR, and Ppeak were measured at 0th minute (basal) and every minute while the surgical procedure lasted. Insufflation pressure was monitored from the laparoscopy device. All other measurements were recorded from the anesthesia device.

Surgical time was defined as time from beginning of skin preparation to completion of umbilical and inguinal wound dressing. Anesthesia time was defined as time from induction to removal of airway device. Recovery time was defined as time from removal of airway device to modified Aldrete score of 9 or above. Events such as aspiration, vomiting, laryngospasm, movement or muscle contraction, response to surgical stimulus, swallowing etc. were noted. Patients were followed for any complications during awakening, recovery and for 2–6 h postoperatively. All patients received 10-mg/kg IV paracetamol preoperatively as well as local anesthetic injection to port site. Patients were taken to recovery room after adequate respiratory effort was observed. Patient was transferred to the ward when the modified Aldrete score was 9 or above, and time was noted. Recovery room and ward staff were blinded to the group of the patients.

1.5. Outcome measures

During the design phase of the study, primary outcome measures were planned as intragastric pressure, P-peak and insufflation pressures and their relationship and secondary outcome measures were planned as time under anesthesia, surgical time and perioperative or postoperative anesthesia-related problems. Methods used when the detailed anesthesia regimes were used or when patients responded to surgical stimuli, the effect of additional drugs on anesthesia and surgical times were later added as secondary measures.

Sample size was determined by authors using data from previous studies [5,13,14].