TIVA With Ketofol Versus Lidoketofol for Short-term Anesthesia on Pediatric Patients; Effects on Recovery

18. December 2020.

METHODS

Patients

Randomized, prospective study will be performed between July 2020 and November 2020. Two hundred pediatric patients aged 1–12 years with an American Society of Anesthesiologists status of I to II, schedule for elective short-term surgery, will be recruited. Hundred will be in the ketofol group and hundred in lidoketofol group. Demographic data including age and sex and also the duration of anesthesia in the two groups will be similar. The children will not be premedicated. If an intravenous (IV) cannula will not be inserted preoperatively, anesthesia will be induced with 4–5% sevoflurane via a face mask. After that, the sevoflurane will be stopped and induction drugs will be administered intravenously.

Intraoperative monitoring

Electrocardiogram (ECG), non-invasive arterial blood pressure, and peripheral oxygen saturation (Draeger-Perseus A500 Anesthesia Device Monitor, Draeger Medical Systems, Inc., Denver, MA) will be used for standard monitoring. A bispectral indeks monitoring system (BIS; BIS™ Brain Monitoring System, Covidien, San Jose, CA) will be used to measure depth of anesthesia. Systolic blood pressure (SBP), mean arterial blood pressure (MAP), diastolic blood pressure (DAP), heart rate (HR), and BIS values will be recorded at 5-min intervals during anesthesia.

Study design

The patients will be randomly allocated into two groups, via a computer-generated randomization list. Ketofol and lidoketofol will be prepared in one syringe. A Draeger™ Module DPS syringe pump (Draeger Medical Systems, Inc., Denver, MA) will be used for infusion of the ketofol and lidiketofol mixture. On arrival at the operating room, standard anesthetic monitoring including non-invasive blood pressure, electrocardiogram and pulse oximeter will be applied. General anesthesia will be induced by ketofol or lidoketofol and fentanyl, and after 20 s, the LMA will be inserted [13]. Mechanical ventilation will be performed to maintain the ET-CO_2 between 35-45 mmHg. Maintenance of anesthesia will be done using air/oxygen (50%/50%) and infusion of ketofol or lidoketofol. Randomization will be performed by random blocks (n=4). Ketofol will be prepared at ratio of 1:4 for induction and 1:7 for maintenance.

Lidoketofol group will be prepared with ketofol at same ratio plus lidocaine. Extubating time waill be defined as the time between discontinuation of the infusion and extubation. The LMA will be removed when spontaneous regular breathing was confirmed. Children will be transferred to the PACU, where respiratory, heart rate and peripheral oxygen saturation (SpO_2) will be recorded. The length of staying in PACU will be defined as time between arrival and discharge time. All patients will be observed for 24 h postoperatively, and will be closely followed for propofol infusion syndrome (PRIS).

Primary and secondary outcomes

The primary outcome of this study will be extubating time. Secondary outcomes will be time spent in the PACU and total opioid consuption.

Statistical analysis

The data weill be analyzed using Statistical Package for the Social Sciences software, version 24.0 (SPSS Statistics for Windows IBM Corp, Armonk, NY). Distributions of quantitative data will be described by medians and interquartile ranges, whereas absolute rates and percentages will be used to describe categorical data. Differences in median values of quantitative variables between the groups of patients will be tested with Mann–Whitney U test. The chi-square test will be used for the statistical analysis of the categorical data. All values of $P<0.05$ will be considered to indicate statistical significance.

Results

Extubating time was significantly lower in lidoketofol group than in ketofol group (120 s versus 240 s; $p < 0.00001$). Length of stay in the PACU was lower in lidoketofol group than in ketofol group (20 min vs. 35 min; $p<0.00001$). Fentanyl (2,1 μg per kg vs. 2,3 μg per kg $P<0.0056$) and propofol (6,6 mg per kg vs. 7,6 mg per kg ; $P<0.032$) consumption per kg were significantly lower in lidoketofol group.

Human Subjects Review:	Board Status: Approved Approval Number: 2181-147-01/06/M.S.-20-12 Board Name: Etičko povjerenstvo Board Affiliation: Klinički bolnički centar Split Phone: +38521556200 Email: eticko.povjerenstvo@kbsplit.hr Address: KBCSplit Spinčićeva 1 Split Hrvatska

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