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Research Article

Effect of intranasal dexmedetomidine or intranasal midazolam on prevention of emergence agitation in pediatric strabismus surgery: A randomized controlled study

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Abstract *Background:* Following strabismus surgery under sevoflurane anesthesia children often experience emergence agitation (EA) and postoperative vomiting (POV). This study compared the effects of premedication with intranasal dexmedetomidine, midazolam, and placebo on postoperative EA and POV.

Methods: 105 children (aged 1–7 years) undergoing elective strabismus surgery under sevoflurane anesthesia were randomly assigned to one of three groups ($n = 35$ each). Preoperatively, group D received intranasal (IN) dexmedetomidine (1 μg/kg), group M received IN midazolam (0.1 mg/kg), and group C received (1 ml) IN normal saline. Agitation scores (Pediatric Anesthesia Emergence Delirium [PAED] scale) and POV were assessed in post-anesthesia care unit (PACU). The incidence of intraoperative Oculocardiac Reflex OCR events, Time to spontaneous eye opening, Postoperative pain score, total consumption of rescue analgesia and time to discharge from PACU were also assessed.

Results: 98 children completed the study. Incidence of agitation (defined as PAED score $\geqslant 10$) was significantly higher in the control group and the midazolam group than in the dexmedetomidine group ($P = 0.014$), and the number of patients who developed severe agitation requiring fentanyl (PAED score $\geqslant 15$) was also higher in the control group ($P = 0.042$).

There was no significant difference between the incidence of POV in the PACU between the control group (28%) and the midazolam group (21%); however, the incidence was significantly lower in the dexmedetomidine group (15%). The number of intraoperative OCR events was significantly higher in the control group (39%) than in the dexmedetomidine (0%; $P = 0.006$) and in the midazolam group the incidence was higher than the dexmedetomidine (9%; 3 events) but did not reach statistical significance.

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Conclusion: Administration of intranasal dexmedetomidine to children undergoing strabismus surgery under sevoflurane anesthesia resulted in a reduced incidence of EA compared with intranasal midazolam or placebo. The incidence of POV and intraoperative OCR was also significantly lower with dexmedetomidine.

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1. Introduction

Emergence agitation (EA) is a complex behavioral disturbance characterized by psychomotor agitation, perceptual disturbances, delusions, and disorientation during recovery from general anesthesia [1]. The incidence of EA in children is higher than in adults ranging from ten to eighty percent [2].

Agitated behavior associated with EA can delay discharge from the post-anesthesia care unit (PACU), decrease parent and caregiver satisfaction, and increase the overall cost to the institution [3]. Risk factors for development of EA include preschool age, previous surgery, ophthalmology or otorhinolaryngology procedures, and inhalation agents associated with fast emergence [4].

Strabismus surgery is one of the most common eye operations in children and it may be associated with significant postoperative pain [5]. Pain can cause distress, anxiety and agitation in children [6]. The oculocardiac reflex (OCR) is another major complication of pediatric strabismus surgery when the heart rate drops to 20% of the resting rate [7]. The incidence of OCR during strabismus surgery has been variously reported between 14% and 90%, depending on premedication and the anesthetic agent used [8,9]. Strabismus surgery is also associated with significant postoperative vomiting (POV) with an incidence of approximately 30% [10], and this contributes significantly to the postoperative distress observed in these children and subsequently limits the use of opioids for pain management after strabismus surgery [11,12].

Sevoflurane is frequently used for pediatric anesthesia because it has low pungency and rapid onset and offset of action [13,14]. The reported incidence of emergence agitation (EA) following sevoflurane anesthesia varies from 10% to 80% between studies, suggesting that EA may depend on numerous factors.

Midazolam is an anxiolytic, sedative, hypnotic, and amnesic drug and is used for premedication in children via several routes [15–19]. Previous studies have shown that intranasal administration of midazolam is easy, effective, and noninvasive, but may cause nasal irritation [20]. Other adverse effects of midazolam include postoperative behavioral changes, cognitive impairment, and respiratory depression [21].

Dexmedetomidine is a potent, highly selective, and specific α2 adrenoreceptor agonist that has both sedative and analgesic effects. Unlike traditional gabaminergic sedative drugs, the primary site of action of dexmedetomidine is the locus coeruleus rather than the cerebral cortex [22]. Therefore, its induced sedation is characterized by an easy and quick arousal from sedation resembling natural sleep [23].

There is evidence that dexmedetomidine decreases the incidence of EA after sevoflurane anesthesia in children undergoing different surgical procedures [24]. It has also been reported that dexmedetomidine can lower the incidence of POV, and decrease the occurrence of OCR during strabismus surgery [25].

The present study was undertaken to investigate the relative benefits of using intranasal dexmedetomidine or midazolam premedication in sevoflurane anesthetized children undergoing strabismus surgery. The primary objective of this study was to compare the effects of intranasal dexmedetomidine and intranasal midazolam on the incidence of EA after sevoflurane anesthesia in children undergoing strabismus surgery. We hypothesized that the incidence of EA would be lower with dexmedetomidine due to its sedative, anxiolytic, and analgesic effects. The secondary objective was to estimate the effects of the two drugs on POV and the incidence of OCR.

2. Methodology

The study was conducted in Magrabi specialist eye hospital between September 2013 and April 2015. Approval by the local Institutional Review Board (IRB), and parental written informed consent were obtained. Children aged between 1 and 7 years of American Society of Anesthesiologists (ASA) physical status I or II undergoing strabismus surgeries were included in this double blind, prospective, randomized study. Primary exclusion criteria included ASA III and IV children, children with developmental delays, any neurological disease associated with symptoms of agitation. Secondary exclusion criteria included parental refusal of consent and allergy to any of the study medications. Of 123 children screened, 105 patients were found eligible and enrolled in the study.

All children were fasted from solid foods for 6 h before the procedure; clear liquids were permitted until 2 h prior to admission to the OR. Before entrance to the OR, Patients were allocated randomly to one of three groups using computer-generated random numbers which were obtained and kept in opaque sealed envelopes that were opened by an independent anesthesiologist not involved in the study: group D, included patients who received intranasal (IN) dexmedetomidine (1 μg/kg), group M included patients who received IN midazolam (0.1 mg/kg), and group C included patients who received IN normal saline. All study drugs were prepared by an anesthesiologist who was blinded to the details of the study.

Parental presence was facilitated during induction of anesthesia. An observer blinded to the group evaluated the modified Yale Preoperative Anxiety Scale (m-YPAS) [26] in the preoperative holding area. Routine monitoring of electrocardiography (ECG), noninvasive blood pressure (NIBP), and Oxygen Saturation (SpO2), were attached before induction of anesthesia and continued during surgery. Anesthesia was induced with 8% sevoflurane in 50% nitrous oxide, and

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