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2023년 8월

석사학위 논문

Comparison of the effects of sugammadex and  
pyridostigmine on postoperative nausea and  
vomiting in pediatric patients undergoing  
strabismus surgery

조선대학교 대학원

의 학 과

정 화 성

Comparison of the effects of sugammadex and pyridostigmine on postoperative nausea and vomiting in pediatric patients undergoing strabismus surgery

소아 사시 수술 환자에서  
슈가마덱스와 피리도스티그민의  
사용에 따른 수술 후 구역 및 구토에  
대한 효과 비교

2023년 8월 25일

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## 국 문 초 록

### 소아 사시 수술 환자에서 슈가마덱스와 피리도스티그민의 사용에 따른 수술 후 구역 및 구토에 대한 효과 비교

정 화 성

지도교수: 임 경 준

조선대학교 대학원 의학과

연구 배경/목적: 수술 후 구역 및 구토(PONV)는 특히 사시 수술에서 소아에게 흔히 발생하며, 잠재적으로 치명적인 부작용이 될 수 있다는 것은 잘 알려져 있다. 수술 자체에 필수적인 마취제와 신경근 차단 역전 약물(NMBRD)이 PONV에 영향을 미친다는 보고가 있다. 최근 소아에서 사용하도록 승인된 슈가마덱스의 사용이 소아의 PONV에 영향을 미치는지 조사하고자 하였다.

환자 및 방법: 사시 수술을 위해 전신 마취를 받는 3~16세 소아 환자 총 40명 (ASA PS I-II)을 대상으로 신경근 차단 역전제의 사용 종류에 슈가마덱스 (그룹 S, n=20), 피리도스티그민 (그룹 P, n=20)따라 두 그룹으로 나누었다. 1차 평가변수는 수술 후(30분 및 1시간, 3시간, 6시간) 박스터 구토증상 척도(BARF)를 사용하여 PONV의 발생률을 비교하였다. 2차 평가변수는 TOF가 0.9 이상으로 회복될 때까지의 시간과 NMBRD 주입 전후의 심박수 변화를 비교하였다.

결과: BARF 척도에 따른 PONV 발생률에는 유의한 차이가 없었다 (30분 시점에서 그룹 S 10% 대 그룹 P 15%, 1시간 시점에서 10% 대 5%). TOF 0.9 이상으로 회복하는 데 걸리는 시간은 그룹 S가 그룹 P보다 유의하게 빨랐으며, 심박수 변동폭은 그룹 S가 유의하게 더 넓었으나 심박수 범위는 정상 범위 내에 있었고, 약물을 사용하지 않고도 수술 전 심박수로 회복되었다.

결론: 소아에서 전신 마취 후 슈가마덱스와 피리도스티그민 PONV 발생률 사이에는 유의미한 연관성이 없는 것으로 나타났다. 슈가마덱스는 소아에서 보다 신속하고 안전하게 신경근 차단역전에 사용할 수 있는 것으로 보인다.

## Abstract

### **Comparison of the effects of sugammadex and pyridostigmine on postoperative nausea and vomiting in pediatric patients undergoing strabismus surgery**

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Background: Postoperative nausea and vomiting (PONV) is a common and potentially fatal side effect in children, particularly after strabismus surgery. Neuromuscular blockade reversal drugs (NMBRDs) used during surgery have been associated with PONV. This study investigated if sugammadex, a recently approved NMBRD for children, induces PONV in this population.

Methods: In total, 40 pediatric patients (3-16 years old, american society of anesthesiologists physical status I-II) undergoing strabismus surgery with general anesthesia were included. They were divided into two groups: sugammadex (group S, n=20) or pyridostigmine (group P, n=20). The primary endpoint was assessing the incidence of PONV using the Baxter Retching Faces (BARF) scale at 30 min and 1, 3, and 6 h. The secondary endpoints included recovery time (train-of-four > 0.9) and changes in heart rate (HR) following NMBRD administration.

Results: There was no significant difference in PONV incidence between the groups according to the BARF scale (Group S: 10% vs. Group P: 15% at 30 min,  $P = 0.471$ ; Group S: 10% vs. Group P: 5% at 1 h,  $P = 0.522$ ). However, sugammadex demonstrated a significantly faster recovery time as compared

to pyridostigmine ( $P < 0.001$ ). Changes in HR were more significant in the sugammadex group than those in the pyridostigmine group ( $P < 0.001$ ); however, HR remained within normal limits and returned to preoperative levels with no rescue medication required during emergence

Conclusion: PONV incidence was not significantly different between sugammadex and pyridostigmine administration in pediatric patients undergoing strabismus surgery. Nevertheless, sugammadex appeared to facilitate faster recovery from the neuromuscular blockade without significant side-effects in this population.

**Key Words:** postoperative vomiting; nausea; neuromuscular blockade reversal; sugammadex; pyridostigmine

# Introduction

For patients undergoing strabismus surgery under general anesthesia, postoperative nausea and vomiting (PONV) is a common and unpleasant experience. The incidence of PONV is higher in children than in adults. It is well known for exhibiting potentially fatal side effects, including dehydration, electrolyte imbalance, impaired wound healing, prolonged hospital stay, delayed recovery from surgery, and significant distress and discomfort to pediatric patients, further leading to adverse psychological and emotional effects. Preoperative fasting and prophylactic pharmacological therapy are commonly used to prevent PONV; however, these drugs can have side effects such as constipation, extrapyramidal symptoms, and arrhythmias.

Conventional neuromuscular blockade reversal drugs (NMBRDs), such as pyridostigmine or neostigmine, have been the only option in children for the reversal of neuromuscular blockade (NMB) in pediatric surgery. Sugammadex is now available for children and has been used safely in adults for over a decade, with reports of a reduced risk of PONV. Similarly, a conventional reversal drug such as pyridostigmine has been reported to cause less PONV than neostigmine in adults. Although several studies have reported comparisons between the effects of neostigmine and of sugammadex on PONV, only a few reported this in children. This study compared the incidences of PONV in pediatric patients after strabismus surgery, depending on the postoperative administration of either pyridostigmine or sugammadex.

## Materials and Methods

The Institutional Review Board of Chosun University Hospital, South Korea, approved this randomized, prospective, double-blind, observational study (IRB No. 2022-006). Informed consent was obtained from the patient's legal guardian. All patients who underwent general anesthesia for strabismus surgery at Chosun University Hospital between January 2023 and April 2023 were included.

The exclusion criteria were as follows: age <3 or >16 years, presence of comorbidities of American Society of Anesthesiologists physical status (ASA-PS) III or higher, presence of congenital conditions (hydrocephalus, hiatal hernia), symptoms of an infection of the upper respiratory tract within the past 2 weeks, and asthma or any other disease of the respiratory tract.

All eligible patients were divided into two groups according to the NMBRD they used, which was administered at the end of general anesthesia (Figure 1). Group S (n=20) received 4.0 mg/kg of sugammadex (Bridion, Kenilworth, NJ, USA). Group P (n=20) received 0.2 mg/kg of pyridostigmine bromide (Pygmin, Hana Pharm, Korea) with 0.01 mg/kg of glycopyrrolate (Tabinul, Hana Pharm, Korea). The NMBRD was prepared in a volume of 4 mL by a nurse blinded to the experimental parameters.

Induction of anesthesia was achieved with 5 mg/kg sodium thiopental (Pentothal sodium; JW Pharmaceutical, Korea), and 2 vol% sevoflurane (Sevofran; Hana Pharmaceutical, Korea) was administered with 5 L/min O<sub>2</sub> through a face mask. After confirmation of loss of consciousness, 0.6 mg/kg bromide of rocuronium (Esmeron; MSD, Kenilworth, NJ, USA) was administered

for muscle relaxation. Anesthesia was maintained with 50% O<sub>2</sub> with N<sub>2</sub>O at a flow rate of 4 L/min with 2 vol% sevoflurane. Quantitative monitoring of neuromuscular function was performed using a train-of-four (TOF) electromyograph (GE healthcare®, GA, USA). No patients received additional regional anesthesia or peripheral nerve block during the perioperative period. At the end of surgery, sevoflurane and N<sub>2</sub>O were stopped and switched to 100% O<sub>2</sub> at 5L/min. When the fourth twitch occurred, the NMB was reversed with the assigned NMBRD—sugammadex or pyridostigmine with glycopyrrolate. The endotracheal tube was removed when the TOF ratio was greater than 0.9, a normal breathing pattern had returned and the face was no longer flaccid. After extubation and confirmation of a normal breathing pattern, the patient was transferred to the post-anesthesia care unit. In the post-anesthesia care unit, the children were kept with their parents. The level of postoperative discomfort was assessed by nurses blinded to the NMBRD. PONV was defined as nausea or vomiting within 6 hours of surgery. The incidence of nausea was assessed using the Baxter Animated Retching Faces (BARF) scale (Figure 2.) Attempting to vomit was considered nausea. Antiemetics were not given routinely but only in the event of vomiting.

Variables and outcome measurements:

- 1) Age, sex, height, weight, body mass index, ASA-PS, and anesthesia time
- 2) Change in heart rate (HR) after NMBRD administration—the difference between basal and maximum HR 1 min after NMBRD administration
- 3) Vomiting immediately after extubation, as measured by an anesthetist blinded to the NMBRD

4) Frequency of PONV using the BARS scale—PONV between 30 min and 1 h after surgery was measured in the post-anesthesia care unit and between 3 and 6 h after surgery, in the ward

The primary endpoint was the estimation of PONV, postoperatively, using the BARS scale, and the secondary endpoints were the elapsed time to TOF greater than 0.9 and changes in HR.

#### Statistical analysis

Statistical analyses were performed using Statistical Package for the Social Sciences (SPSS, version 27.0, IBM Corp., NY, USA). Continuous variables are presented as mean  $\pm$  standard deviation, and categorical variables are presented as the number of patients (%). The normality of the distribution was evaluated using the Shapiro-Wilk test. All data were found to be normally distributed. The Chi-squared test was used to compare the incidence of PONV using the BARS scale, which was the primary goal of the study. To determine any association between NMBRDs and PONV, odds ratios (OR) and 95% confidence intervals (95% CI) were used. The Chi-squared test was used to analyze sex and the category of ASA-PS. t-tests were used to analyze age, sex, body mass index, and duration of anesthesia. Changes in HR were analyzed by repeated measures two-way analysis of variance, and differences between groups were analyzed by t-test. Tukey's honestly significant difference test was used for post hoc testing. Statistically significant was defined as a P value  $<0.05$ . Body mass index (BMI) was categorized according to the WHO classification. ORs for the incidence of PONV within 6 h after surgery were calculated using logistic regression analysis.

## Results

A total of 40 patients were eligible for inclusion in the study. Baseline characteristics and duration of anesthesia were not significantly different between groups. (Table 1).

The primary endpoint, PONV incidence, assessed using the BARS scale, was not significantly different between the two groups. The secondary endpoints, time to recovery from TOF 0.9 and above, was significantly faster in group S, and changes in HR were significantly greater in group S than those in group P (Table 3). The changes in HR were controlled over time (Table 4). No emergency bradycardia control medications or antiemetics were required in either group.



## Discussion

Sugammadex is a gamma-cyclodextrin that encapsulates and subsequently inactivates steroidal NMBDs and has the highest affinity for the most commonly used NMBDs. It has been proposed that there is an association between NMBRD and PONV outcomes and that similar reversal drugs may act on the emetic center and PONV may be caused by muscarinic receptor effects. Glycopyrrolate combined with pyridostigmine may also prevent PONV after laparoscopic surgery and Cesarean section under neuraxial anesthesia. However, in patients who have received opioid-based intravenous patient-controlled analgesia, sugammadex may be more beneficial than pyridostigmine for PONV.

Recently, some meta-analyses of PONV after the use of NMBRDs have reported sugammadex to have potential advantages over neostigmine, similar to those of pyridostigmine in the rate of PONV after general anesthesia (OR=0.64, [0.46–0.90]). However, use in pediatric patients is recent; hence, there are no meta-analysis reports on their effects on PONV. However, studies have reported inconsistent results regarding the effects of NMBRDs on neuromuscular blockade.

The incidence of PONV in adults has been reported in several studies. The incidence of PONV at 6 hours after ENT surgery was significantly lower in patients receiving sugammadex (3%) than in those receiving the neostigmine-atropine combination (20%) ( $p = 0.013$ ). Based on this, we decided to actively investigate the incidence of PONV up to 6 h postoperatively.

Additionally, it is important to note that PONV is a multifactorial problem;

thus, many other factors may contribute to its development in pediatric patients. Eberhart's simple risk score for predicting the risk of postoperative vomiting in children score takes into account the time of surgery, age, strabismus surgery, and a family history of previous vomiting. This risk score shows that the incidence of vomiting increases as risk factors accumulate. Based on this, some studies have developed pediatric-specific risk scores to predict the risk of vomiting. For PONV, patients with an Apfel simple score of 2 or more are candidates for intraoperative management. Moreover, managing PONV in pediatric patients should be customized individually, based on the specific risk factors of the patient and the type of surgery to be performed. This may also include the use of anti-nausea medications such as ondansetron, the use of local anesthetics, or non-pharmacological interventions, such as acupuncture or acupressure.

Sugammadex did not differ significantly from neostigmine in clinically meaningful bradycardia, hypersensitivity, or anaphylaxis. These results support the use of sugammadex to reverse moderate and deep rocuronium- and vecuronium-induced NMB in patients (aged 2-17 years) using sugammadex (4 mg/kg). Thus, we studied the pediatric population (age, 3–16 years).

It is difficult to objectively assess nausea in children; therefore, vomiting is used as an objective clinical endpoint to manage postoperative or post-discharge nausea in children. The BARF scale can be used for this purpose. The BARF is a pictorial rating scale developed to assess PONV in children. It consists of five cartoon faces, ranging from happy to very unhappy, with the fifth face depicting a child vomiting. (Figure 2) Children are asked to point to the face that best represents how they feel. The BARF scale is a reliable and valid tool for assessing PONV in children. It has been

used in clinical trials and practices to assess the effectiveness of antiemetics and other interventions for PONV. A score of 4 or more on the BARF scale is recognized as requiring rescue antiemetics, making it easy to use in clinical practice in pediatric patients (age,  $\geq 6$  years), with a minimum clinically important difference of 1.47. Therefore, this cut-off value was used in the OR in patients in this study.

This trial had limitations. First, at the time the study was designed, there was no prior study data on these times. Therefore, the neostigmine study was used to calculate the sample size. In addition to the BARF scale, several indicators of adequate postoperative PONV monitoring should be used and compared. This is because assessment using the BARF scale has shown that clinically significant nausea is common in children, but is not always managed except when it is coupled with vomiting. As previous studies have shown that gastric decompression (GD) prevents POV in children, the use of GD in both groups for patient safety may have led to a reduction in the incidence of POV. The comparison should be made in patients undergoing the same type of surgery to be accurate (which muscles are affected in strabismus and binocular vs. monocular). Long-term post-discharge nausea and vomiting also should be studied because of the longer duration of action of pyridostigmine. Another limitation is that we do not measure PONV laboratory parameters such as C-reactive protein, aldehydes and ketones. The timing of the administration of sugammadex and pyridostigmine may need optimization. Sugammadex tends to be given earlier when it is more likely to be associated with the residual effect of volatile anesthetics. In contrast, pyridostigmine should be given at a TOF count of 2 or higher, which can lead to a different HR before NMBRD injection. Moreover, glycopyrrolate, an

anticholinergic, was used only in group P in combination with pyridostigmine to prevent bradycardia, a side effect of pyridostigmine. This may explain the relatively small change in HR. In future, the combination of sugammadex and glycopyrrolate could be considered for similar conditions, although no bradycardia requiring treatment occurred in this study. As there is already a trial looking at whether glycopyrrolate itself can help prevent PONV, it differs from this trial because it is related to the use of opioids and not the surgery itself.

Overall, although pyridostigmine may not significantly increase the risk of PONV in children, it is important to be aware of its potential side effects and to use it judiciously as part of a comprehensive anesthetic regimen. Close monitoring and individualized management of PONV can help minimize its impact on pediatric patients after surgery. It is also important to note that pediatric use of sugammadex is relatively new; therefore, there is a need for further studies to confirm the efficacy and safety of sugammadex. As with any medication, the risks and benefits of sugammadex should be carefully considered by the healthcare provider and discussed with patients and their families.

In conclusion, PONV can result from several central and peripheral mechanisms. As an integral part of general anesthesia, there are several drugs used in surgery that can directly or indirectly cause vomiting. Many of these drugs have no substitutes, and their long history of relatively safe use and perceived safety makes it difficult to switch easily from one drug to another simply because it causes PONV. The value of several recently published studies of sugammadex showing a reduced risk of PONV in adults may be even greater in children. Therefore, sugammadex can be used as an

alternative to drugs such as anticholinesterases, which have a long history of use in adults and have not yet been shown to improve PONV.

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Table 1. Demographic data

Variable	Group S (n=20)	Group P (n=20)	P-value
Age (years)	8.2 ± 2.9 (6.93–9.47)	8.3 ± 2.5 (7.2–9.4)	0.953
Sex (M/F)	(11/9)	(11/9)	1.000
BMI	19.4 ± 4.0 (17.6–21.1)	19.1 ± 5.2 (16.8–21.4)	0.840
ASA-PS class (I/II)	(20/0)	(17/3)	0.072
Anesthesia Time (min)	66.5 ± 11.1 (61.6–71.4)	68.9 ± 9.7 (64.7–73.2)	0.471

Data are provided as mean ± standard deviation (95% confidence interval).

The level of statistical significance is set at  $P < 0.05$ . Group S, sugammadex; group P, pyridostigmine; ASA-PS: American Society of Anesthesiologists physical status; BMI: body mass index

Table 2. The incidences of PONV by BARF scale over time

Time after emergence	Group S (n=20)	Group P (n=20)	P-value	OR
30 min	2 (10%)	3 (15%)	0.471	0.482 (0.066–3.514)
1 h	2 (10%)	1 (5%)	0.522	2.431 (0.161–36.789)
3 h	0	0	-	-
6 h	0	0	-	-

Values are provided as incidence (%). Group S, received sugammadex (4.0 mg/kg); Group P, received pyridostigmine bromide (0.2mg/kg) with glycopyrrolate (0.01 mg/kg); PONV, postoperative nausea and vomiting; BARF, Baxter Retching Faces; OR, odds ratio.

Table 3. Changes upon recovery from anesthesia

Variables	Group S (n=20)	Group P (n=20)	P-value
TOF >0.9 time (s)	62.7 ± 27.0 (50.9–74.5)	125.9 ± 47.6 (105.3–147.1)	<0.001
Heart rate variation (%)	13.9 ± 11.2	0.3 ± 11.7	<0.001

Data are provided as mean ± standard deviation (95% confidence interval).

Group S, received sugammadex (4.0 mg/kg); Group P, received pyridostigmine bromide (0.2mg/kg) with glycopyrrolate (0.01 mg/kg). Heart rate variation represent the changes in minimal and maximal HR before and after NMB reversal drug injection. TOF, train-of-four;

Table 4. Changes in heart rate over time

Changes in HR	Group S (n=20)	Group P (n=20)	P-value
Baseline (before induction)	97.6 ± 15.4 (90.8–104.1)	101.4 ± 13.8 (95.4–107.5)	0.416
Before HR NMBRD use	92.8 ± 19.8 (84.1–101.4)	100.5 ± 17.5 (92.8–108.3)	0.201
After HR NMBRD use	80.4 ± 22.6 (70.5–90.3)	100.3 ± 18.6 (92.1–108.9)	0.004
PACU (30 min after NMBRD)	103.3 ± 15.8 (96.4–110.5)	101.5 ± 13.0 (95.8–107.2)	0.688

Data are provided as mean ± standard deviation (95% confidence interval).

Group S, received sugammadex (4.0 mg/kg); Group P, received pyridostigmine bromide (0.2mg/kg) with glycopyrrolate (0.01 mg/kg). HR, heart rate; NMBRD, neuromuscular blocking reversal drug; PACU, post anesthesia care unit

### Legend for figures

Figure 1. Study flow diagram. Enrollment of 40 pediatric patients (3–16 years of age) undergoing general anesthesia for strabismus surgery (American Society of Anesthesiologists physical status I-II) and their randomization into two groups according to the NMBRD used: Group S, received sugammadex (4.0 mg/kg); Group P, received pyridostigmine bromide (0.2mg/kg) with glycopyrrolate (0.01 mg/kg). NMBRD, neuromuscular blockade reversal drug.

Figure 2. BARF scale: Six faces with allocated scores ranging from 0 to 10. The score difference between each face is 2 (a higher score indicates more nausea). The script for the BARF scale: "Have you ever thrown up or felt like you were going to throw up? What did your stomach feel like? We call this feeling of being sick to your stomach nausea. These faces show children who feel no nausea at all, who feel a little nauseous, who feel more nauseous, and these children have the most nausea that can be felt. (Point to each face at the appropriate time.) Which face is more like how you feel right now?"

Figure 1.

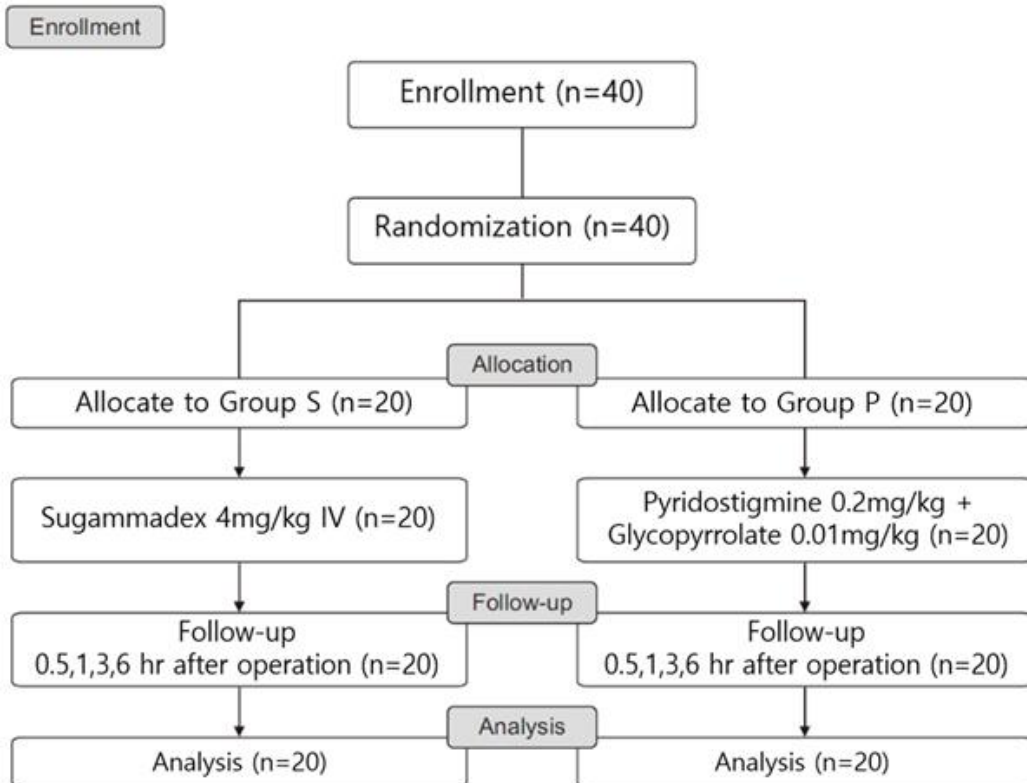


Figure 2.

