Sub-Tenon’s injection versus paracetamol in pediatric strabismus surgery

ABSTRACT

Background: Emergence agitation, vomiting, and oculocardiac reflex (OCR) in children undergoing strabismus surgery under general anesthesia are common problems. The purpose of this study was to determine whether the effect of analgesia can reduce the incidence of these problems. We compared the effects of sub-Tenon’s injection versus intravenous (IV) and rectal paracetamol in this surgery.

Methods: In a prospective, randomized, double-blind study, ninety patients ranging in age from 4 to 8 years scheduled for extraocular muscle surgery for strabismus were included in this study. After induction of anesthesia, just before the surgery, children were divided into three groups (n = 30 for each group) Group A received sub-Tenon’s anesthesia with 2.5% bupivacaine (0.08 ml/kg). Group B received IV paracetamol (20 mg/kg). Group C received paracetamol rectal suppository (40 mg/kg). The occurrence of oculocardiac reflex (OCR) intraoperatively was recorded. Then, in the Postanesthesia Care Unit, patients were assessed for their emergence behaviors. Vomiting was also noticed.

Results: The OCR developed in few patients, and there was no significant difference between the groups. The highest number of patients with agitation was in Group C followed by Group B then Group A. Vomiting was significantly low in Group A followed by Group B then Group C.

Conclusion: Sub-Tenon block in strabismus surgery in children decreased the incidence of postoperative agitation and vomiting compared with IV paracetamol then rectal paracetamol. There was no difference between sub-Tenon block and paracetamol in the incidence of oculocardiac reflex.

Key words: Paracetamol, strabismus surgery, sub-Tenon’s injection

Introduction

Strabismus surgery is one of the most frequently performed pediatric ocular operations,[1] and it requires general anesthesia. For decades, halothane was the predominant anesthetic that was given to children. However, the introduction of the short acting volatile anesthetics such as sevoflurane did not solve the common problem of emergence agitation in children.[2]

Postoperative pain management markedly decreases the emergence agitation in children. Because of potential side effects, opiates, and nonsteroidal anti-inflammatory
drugs are not commonly used. Intravenous (IV) and rectal paracetamol were proved to be effective in controlling pain in these cases.[3]

Recently, regional anesthesia techniques have been recommended in conjunction with general anesthesia. Sub-Tenon’s block is one of these techniques used in ocular surgery. This technique involves local anesthetics being injected into the sub-Tenon’s space.[4,5]

Typically, the major problems associated with strabismus surgeries include increased the risk of the oculocardiac reflex (OCR) (32–90%). This reflex may occur in response to a retraction of the extraocular muscles and is associated with an increased postoperative nausea and vomiting (PONV) incidence (46–85%) resulting from the oculo-emetic reflex.[6]

The purpose of this study was to determine the effect of a sub-Tenon’s injection versus IV and rectal paracetamol on oculocardiac reflex and emergence agitation in children who had received sevoflurane or halothane anesthesia for strabismus surgery.

Methods

After obtaining approval from the Ethics and Research Committee of the Department of Anesthesia and written informed consent from the parents of the study participants, this prospective randomized controlled study was conducted in the Ophthalmic Surgery Department of Ainshams University hospital between September 2015 and February 2016. A total of ninety American Society of Anesthesiologists Status I and II boys and girls, ranging in age from 4 to 8 years scheduled for extraocular muscle surgery for strabismus were included in this study.

Children in whom intubation was expected to be difficult, and those with significant cardiac, respiratory, renal, hepatic, or neurological disorders were excluded from the study. All patients fasted for 6–8 h. Procedures were performed in the early morning after premedication with midazolam 0.5 mg/kg orally, 30 min before induction. Children were continuously monitored in the operating room by electrocardiography and pulse oximetry (oxygen saturation), and for blood pressure and end-tidal carbon dioxide. An IV cannula was placed. Anesthetic induction was carried out with propofol (2–2.5 mg/kg) for all children and tracheal intubation with an appropriately sized uncuffed tube was facilitated with atracurium (0.5 mg/kg). After induction of anesthesia, children were divided into three groups (n = 30 for each group) using a computer-derived randomization list. Group A received sub-Tenon’s anesthesia with 2.5% bupivacaine (0.08 ml/kg). Under sterile conditions, a 19-gauge curved, blunt metallic cannula (25 mm) was inserted into the sub-Tenon’s space by the surgeon and the local anesthetic was slowly injected, then manual compression was performed. Group B received IV paracetamol (20 mg/kg). Group C received paracetamol rectal suppository (40 mg/kg). After 5 min, surgery started. Anesthesia maintenance was performed with sevoflurane or halothane. The dose of sevoflurane or halothane was adjusted to maintain heart rate and blood pressure within 20% of baseline values. Controlled ventilation was selected to maintain end-tidal CO2 values between 30 and 35 mmHg. Oculocardiac reflex (OCR) was considered as an acute decrease in heart rate below 60 beats/min. If this happens, the surgical stimulus will be withdrawn. If a patient did not respond, atropine (0.01 mg/kg) was given. Intraoperative follow-up was performed by an anesthesiologist blinded to study groups. Anesthetic administration was discontinued at the end of surgery and patients were extubated by an antagonizing neuromuscular block with neostigmine (50 microgram/kg) and atropine (0.01 mg/kg) with resuming adequate spontaneous breathing and a gag reflex. The patients were then transferred to the Postanesthesia Care Unit. On arrival at the Postanesthesia Care Unit, two trained observers, blinded to the patient’s treatment group, assessed and rated his or her emergence behavior using the five-point scoring system for emergence delirium described by Cole et al. (1) asleep, (2) awake and calm, (3) irritable behavior or consolable crying, (4) inconsiderable crying, and (5) severe restlessness.[7]

Scores were recorded on arrival in the Postanesthesia Care Unit. Vomiting was also noticed. If agitation was continuous or severe, propofol (1–2 mg/kg) was administered IV and antiemetics were prescribed for severe nausea and vomiting. Children were discharged from the Postanesthesia Care Unit when they met the discharge criteria, including stable vital signs, being fully awake, oxygen saturation >95% of room air, and the absence of vomiting and agitation. For statistical purposes, children with an agitation score of 4 or 5 were classified as agitated.

Statistical analysis

A group size of ninety was chosen, based on previous studies 4, 6, 7 with an α = 0.05 and a power of 0.8.

Data were compared using analysis of variance, and continuous data were presented as a mean ± standard deviation. Data were analyzed using the SPSS® version 14.0 (SPSS, Chicago, IL, USA). P < 0.05 was considered to be statistically significant.
Primary outcomes were to detect the incidence of OCR and postoperative agitation, while the secondary outcome was to detect the incidence of postoperative vomiting in the groups.

**Results**

There were no significant differences between groups regarding age, gender, weight, number of muscles operated on, and operation times [Table 1].

The OCR developed in few patients, and there was no significant difference between the groups [Table 2 and Figure 1]. Atropine (0.01 mg/kg) was given to these patients after removal of the surgical stimulus with successful termination of the reflex.

Upon arrival in recovery room, few patients showed agitation \((n = 2)\) in Group A compared with Group B \((n = 8)\) and C \((n = 16)\). The highest number of patients with agitation was in Group C and that was statistically significant. Exactly half of the patients \((n = 45)\) received halothane and the other half received sevoflurane in the surgery. The total number of patients who showed agitation was 26 out of 90. Twelve of them received halothane, while 14 received sevoflurane with no significant difference between them. Agitated patients received small doses of propofol. Vomiting was observed in 1 patient in Group A, 6 patients in Group B, and 13 patients in Group C and that was statistically significant [Table 3 and Figure 2]. Antiemetics were given to those children.

**Discussion**

The aim of the present study was to estimate the effect of a sub-Tenon’s bupivacaine injection versus paracetamol IV or rectally in children who had received general anesthesia for strabismus surgery.

| Table 1: Age, sex, weight and operative details data |
|-----------------------------------------------|
|                              | Group A     | Group B     | Group C     | T-test |
| Age in years                  |             |             |             |        |
| Mean±SD                       | 6.2±1.2     | 5.7±1.3     | 6.3±1.4     | 1.827  |
| Sex                           |             |             |             | 0.167  |
| Male                          | 16±53.3     | 18±60.0     | 17±56.7     | 0.271  |
| Female                        | 14±46.7     | 12±40.0     | 13±43.3     | 0.873  |
| Weight (kg)                   |             |             |             |        |
| Mean±SD                       | 20.1±2.3    | 18.8±1.8    | 19.5±2.4    | 2.666  |
| Number of muscles             |             |             |             | 0.075  |
| Mean±SD                       | 2.1±0.2     | 2.0±0.3     | 2.1±0.3     | 1.364  |
| Operation time in minutes     |             |             |             | 0.261  |
| Mean±SD                       | 57.6±5.7    | 60.3±7.1    | 56.4±6.4    | 2.899  |
| SD: Standard deviation        |             |             |             |        |

| Table 2: OCR incidence        |
|--------------------------------|
| OCR                           | Group A     | Group B     | Group C     | Chi-square test |
|                               | \(n=30\)    | \(n=30\)    | \(n=30\)    | \(\chi^2\)    |
| Yes                           | 6 (20)      | 7 (23.3)    | 7 (23.3)    | 0.129          |
| No                            | 24 (80)     | 23 (76.7)   | 23 (76.7)   | 0.937          |

| Table 3: Agitation and vomiting incidence |
|-------------------------------------------|
| Agitation, \(n\) (%)                      | Vomiting, \(n\) (%) |
| Group A                                  | 2 (6.7)          | 1 (3.3)      |
| Group B                                  | 8 (26.7)         | 6 (20.0)     |
| Group C                                  | 16 (53.3)        | 13 (43.3)    |
| Chi-square test                           |                |
| A and B                                  | \(\chi^2\) | 4.320        | 4.043        |
| \(P\)                                    |          | 0.038*       | 0.044*       |
| A and C                                  | \(\chi^2\) | 15.556       | 13.416       |
| \(P\)                                    |          | <0.001*      | <0.001*      |
| B and C                                  | \(\chi^2\) | 4.444        | 3.776        |
| \(P\)                                    |          | 0.035*       | 0.049*       |

*statistically significant
Strabismus surgery is a common ocular surgery in children, and it has some risks. One of them is the OCR. OCR, a trigeminal–vagal reflex response manifesting as cardiac arrhythmias and hypotension, occurs in response to retraction of extraocular muscles during strabismus surgery. Several maneuvers have been proposed to eliminate or reduce OCR in the literature. However, none of these methods are considered effective, safe, or acceptable.\[^{1,8}\] Even anticholinergic agents for premedication sometimes may not decrease the incidence of OCR significantly.\[^{9}\] As these surgeries are mostly performed under general anesthesia, the incidence of agitation is relatively high because sevoflurane and halothane are associated with emergence agitation. Occurrence rates range from 10 to 80%.\[^{10-13}\] Although some authors suggest that emergence agitation occurs despite adequate pain relief,\[^{14}\] or even in the absence of any painful stimulus,\[^{10,15}\] pain should be regarded as a major contributing factor.

Paracetamol remains the reference analgesic with good clinical efficacy without adverse reactions on the gastrointestinal tract and hematomatological system. True allergies for paracetamol are rare. Analgesic activity of paracetamol depends on the speed and level of the peak plasma concentration. In children, rectal paracetamol is widely used in the treatment or prevention of postoperative pain.\[^{1,8}\] Several studies have shown that indeed, rectal paracetamol in doses recommended by the manufacturers is ineffective.\[^{16}\] Morton and Arana\[^{17}\] recommend to start with an initial IV dose of 20 mg/kg or a rectal dose of 40 mg/kg. Maximum daily dose is limited to 90 mg/kg.

Regional anesthesia is used as an adjunct to general anesthesia in children. Several studies have reported that preoperative regional blocks reduce the need for intraoperative anesthetic and contribute to postoperative analgesia.\[^{18-20}\] As sub-Tenon’s block is performed under direct visualization, it provides a safe anesthesia with minimal risk for severe complications.\[^{21}\]

Our study goes with the results of Sheard et al.\[^{22}\] which showed that sub-Tenon's block provided good analgesia after strabismus surgery in children using lidocaine, but the block was done by the end of the surgery. In our study, we used bupivacaine (which has a longer duration than lidocaine) at the start of the operation so that we could evaluate the block efficacy as regards OCR and prolong the duration of postoperative analgesia.

Steib et al.\[^{4}\] reported a significant reduction in OCR and postoperative vomiting when using sub-Tenon’s block combined with general anesthesia compared with the control group who received sub-Tenon saline injection. However, they did not compare the block with systemic analgesia. OCR percentage in their study was 18% in sub-Tenon’s group, while postoperative vomiting percentage was 22%. Our study showed a closer percentage in OCR in all groups (20–23%) with no significant difference between them but marked decrease in postoperative vomiting percentage (3.3%) in Group A followed by Group B (20%) then Group C (43.3%).

Pain is a contributing factor to vomiting,\[^{22}\] so the apparent good pain control achieved by sub-Tenon block markedly decreased the incidence of postoperative vomiting. However, it is important to emphasize that postoperative vomiting in strabismus surgeries are multifactorial. It has been suggested that “oculo-emic reflex” is responsible for the high incidence of vomiting following strabismus surgery. Intraoperative recession and manipulation should cause more traction on eye muscle spindles, thus, via vagal and trigeminal afferents activate the vomiting system. Another hypothesis is based on an optokinetic imbalance and disturbance of visual axes. Age, sex, duration of anesthesia, and history of PONV are also risk factors.\[^{23}\]

Our study goes with the study done by Tuzcu et al.\[^{24}\] which showed that sub-Tenon’s block combined with general anesthesia produced significant analgesia postoperatively but they found that the block was not effective in decreasing oculocardiac reflex and postoperative vomiting which was against our study. However, their study was on a lower number of patients (40).

Few cases showed agitations in all groups, probably because although pain is the primary relevant factor, there are also other contributing factors such as metabolic disturbances, bladder distension, hypoxemia, preexisting psychosocial pathology, physiological abnormalities (double vision), rapid emergence, a hostile or unfamiliar environment, low adaptability, preoperative anxiety, an increase in the use of specific inhalational agents, and residual drug effects.\[^{25}\] However, Group A showed a marked decrease in the incidence of agitation followed by Group B followed by Group C which proves that pain control was better achieved by sub-Tenon block.

This goes with the study done by Elgebaly\[^{26}\] which showed that the incidence of emergence agitation was significantly reduced by a sub-Tenon's lidocaine injection, regardless of the modality of anesthesia used. The study also showed that the emergence agitation was significantly higher following sevoflurane than halothane anesthesia. However, in our study, there was no significant difference between...
halothane (12 patients) and sevoflurane (14 patients) as regards emergence agitation.

Conclusion

Sub-Tenon block in strabismus surgery in children provides better pain control as evidenced by a decrease in the incidence of postoperative agitation and vomiting compared with IV and rectal paracetamol. IV paracetamol was better to control pain than rectal paracetamol. There was no significant difference between sub- Tenon block and paracetamol in the incidence of oculocardiac reflex.

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Conflicts of interest
There are no conflicts of interest.

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