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Comparative study between combined general anesthesia with peribulbar block versus traditional general anesthesia in patients undergoing strabismus surgery

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Abstract

Introduction: Strabismus is a common ophthalmic problem that usually requires surgical correction. However, general anesthesia is mandatory for most cases, concomitant local anesthetics administration is preferable to improve patient satisfaction, decrease post-operative analgesic requirements, post-operative pain and oculocardiac reflex (OCR), which is a noted serious com-plication that accompanies such surgeries.

Aim of the study: The study aimed to evaluate the efficacy of adding peribulbar block (PBB) to general anesthesia on incidence of oculocardiac reflex, postoperative pain, nausea, and vomiting (PONV) in patients undergoing unilateral strabismus surgery.

Subjects and Methods: 70 patients undergoing strabismus surgery were recruited in the current study. Participants were equally divided into two groups; Group (1) didn't receive PBB, while Group (2) had a combination of general anesthesia and PBB. Pain evaluation by visual analog score (VAS) was assessed at 2-, 6-, 12-, and 24-hours post-operation.

Results: Incidence of OCR was higher in group (1) than in group (2) (25.7% vs. 5.7%), which was a statistically significant, *P=0.022.* Also, incidence of nausea and vomiting (PONV) was a statistically significantly higher in group (1) than in group 2 (42.9% vs. 17.1%), *P=0.019.* As regarding VAS score for pain was statistically significantly lower in group (2) than group (1) at two hours (40 vs. 20), six hours (40 vs. 20), twelve hours (20 vs. 0), and twenty-four hours *P<0.0001.*

Conclusion: PBB had a great benefit in strabismus surgery when combined with general anesthesia. It reduced the incidence of OCR, post-operative pain score, and PONV.

Keywords: Peribulbar block; oculocardiac reflex; strabismus

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1. Introduction

Strabismus is a common ophthalmic problem that usually requires surgical correction. However, General anesthesia is mandatory for most cases, the concomitant local anesthetics administration is preferable to im-prove patient satisfaction, decrease post-operative analgesic requirements, post-operative pain and oculocardiac reflex

(OCR), which is a noted serious complication that accompanies such surgeries [1-2].

OCR is one of main challenges during strabismus surgery for anesthesiologists [3]. Its incidence ranges from 16-82 %, and this wide range does depend on the anesthetic agents, premeditations, and the definition of used OCR. Maintenance of adequate depth of anesthesia and the use of anti-cholinergic is the mainstay to reduce this risk [4]. OCR is usually defined as a decrease in heart rate of more than 20 % from the baseline [5]. This reflex is triggered by the pressure on the extra ocular muscles (EOM) or eyeball, orbital hematoma or trauma [6], the afferent limb is from orbital contents to ciliary ganglion, then to the sensory nucleus of the trigeminal nerve near the fourth ventricle through the ophthalmic division of the trigeminal nerve [7]. The reflex is transmitted via the vague nerve to the heart. The vagal stimulation leads to bradycardia and arrhythmias symptoms, such as atrio-ventricular block, ventricular fibrillation, and even car-diac arrest [8].

The incidence of the OCR decreases with age and tends to be more pronounced in young healthy patients [9]. It has been suggested that the anesthetic agents used during surgery influence the incidence of OCR. To date, the first method to interrupt an OCR is to stop the EOM traction and to proceed with cautions while surgery continues. Depth of anesthesia is another method of reducing OCR incidence [10].

The objective of the current study was to evaluate the efficacy of adding peribulbar block (PBB) to general anesthesia in reducing the incidence of OCR in patients undergoing unilateral strabismus surgery and to evaluate the effect of PBB with general anesthesia on PONV and post-operative pain.

2. Subjects and methods

2.1. Subjects

The current study recruited 70 patients undergoing strabismus surgery after approval of the local institutional ethics committee and local institutional review board. The study was prospective, randomized, parallel groups, controlled clinical trial. A detailed informed consent was signed by the eligible participants before recruitment and randomization.

2.2. Inclusion criteria

Patients were recruited as they aged 10-50 years, had the American society association (ASA) physical status I, II, and undergoing Unilateral strabismus sur-gery.

2.3. Exclusion criteria

Patients who either refused local anesthesia, had contra indications of local anesthesia, or underwent bi-lateral strabismus surgery were excluded.

2.4. Study design

The Consolidated Standards of Reporting Trials (CONSORT) recommendations for reporting random-ized, controlled clinical trials had been followed.

70 pa-tients were randomly divided into two groups, each group had 35 patients;

Group 1: Total 35 cases received general anesthesia only, i.e., without PBB.

Group 2: Total 35 cases received general anesthesia with PBB.

2.5. Intraoperative technique and management

Upon arrival to the operating room standard monitors and a peripheral intravenous (IV) cannula were inserted. After adequate pre-oxygenation, Induction was accomplished with the injection of Fentanyl 1 µg/kg IV and propofol 2 mg/kg. Endotracheal intubation was facilitated by the intravenous injection of 0.5 mg/kg atracurium. General anesthesia had been maintained by mechanical ventilation with oxygen and air (50:50), isoflurane.

Patients in group 2 received PBB with mixture of Lidocaine 1%, bupivacaine 0.25% and Hyaluronidase 7.5IU/mL by 23G needle after intubation. Intraoperative OCR was managed by asking the operator to stop the surgical traction and giving 0.01 mg/kg of atropine. At the end of surgery, Participant had been transferred to postoperative anesthesia care unit with standard monitoring applied. Pain was evaluated by visual analog score (VAS) score from (0_ 100) (where; zero = no pain, 100=worst imaginable pain) assessed at 2, 6, 12, 24hours postoperative.

2.6. Statistical analysis and sample size estimation

The collected data were organized, tabulated and statistically analyzed using SPSS software statistical computer package version 18 (SPSS Inc, USA). Numerical variables were normally distributed and were described as mean ± standard deviation. An independent t-test was used to compare the mean values of the two groups. Other variables were not normally distributed and were presented as median and range; Mann-Whitney U test was used as a test of significant. Qualitative data were presented as numbers and percentages, and the chi-squared test was used to determine significance. A two-sided *P-value<0.05* was considered statistically significant.

Sample size was calculated using (G power version 3). Minimal sample size of patients was 32 in each group needed to get power level 0.80, alpha level 0.05 and 20% difference between groups in OCR. To overcome problem of loss of follow up, calculated sample size was increased by 10% to reach 35 in each group.

3. Results

There was no statistically significant difference between study groups in age and sex. Incidence of OCR was higher in group 1 than in group 2 (25.7% vs. 5.7%), which was statistically significant, *P=0.022.* Also, the incidence of PONV was statistically significantly higher in group 1 than in group 2 (42.9% vs. 17.1%), *P=0.019.*

Regards the VAS pain score, it was statistically significantly lower in group (2) than in group (1) at 2 hours (40 vs. 20), 6 hours (40 vs. 20), 12 hours (20 vs. 0), and 24

hours *P<0.0001*. The results of the present study are demonstrated in Tables 1, 2, and 3.

Table 1: Comparison of Socio-demographics between different groups.

		Group 1	Group 2	*P-value*
Frequency		35	35	
Age (years) Mean ±SD		21.9±9.6	20.5±8.1	0.495#
Sex N (%)	Female	19 (54.3%)	24 (68.6%)	0.220##
	Male	16 (45.7%)	11 (31.4%)	

#Independent-t test, ##Chi-squared test, SD=standard deviation.

Table 2: Comparison of Incidence of OCR and PONV among different study groups.

		Group 1 (N=35)	Group 2 (N=35)	*P-value#*
Incidence of OCR	No	26 (74.3%)	33 (94.3%)	0.022*
	Yes	9 (25.7%)	2 (5.7%)	
Nausea & vomiting	No	20 (57.1%)	29 (82.9%)	0.019*
	Yes	15 (42.9%)	6 (17.1%)	

#Chi-squared test; *Significant.

Table 3: Comparison of Incidence of OCR and PONV among different study groups.

VAS	Group 1 (N=35)	Group 2 (N=35)	*P-value#*
2 hours	40 (0-60)	40 (0-40)	<0.0001*
6 hours	40 (0-40)	40 (0-40)	<0.0001*
12 hours	40 (0-50)	40 (0-20)	<0.0001*
24 hours	40 (0-40)	40 (0-0)	<0.0001*

Mann-Whitney U test; *Significant.

4. Discussion

In this randomized controlled trial, we studied the combination of PBB with general anesthesia as a method to decrease the incidence of OCR during strabismus surgery. That agreed with Deb *et al.,* (2001), who studied 50 children for elective ophthalmic surgery 25, received intravenous pethidine (control group), and 25 received PBB (block group) for perioperative analgesia. The incidence of OCR was significantly higher (*P<0.001*) in the control group [11].

Also, the study conducted by Kim and Shin (2018) evaluated the incidence of OCR during strabismus surgery involving medial rectus resection. They found that applying prophylactic intratracheal block significantly reduced the incidence of OCR [12].

In the current study, intraoperative OCR was managed by asking the operator to stop the surgical traction and giving 0.01 mg/kg of atropine. There was a significant difference in the number of patients who required the use of atropine. That was coexisting with Ghali and El Btarny (2010), who studied sixty adult patients undergoing elective primary retinal detachment surgery with scleral buckling or an encircling procedure received either PBB in conjunction with general anesthesia or general anesthesia alone. In the block group, there was a lower incidence of OCR, and a higher incidence of bradycardia requiring atropine administration in the GA group [13].

Gupta *et al.*, (2007) found that topical anesthesia drops were only marginally effective in obtunding the OCR, whilst the PBB was more effective by anesthetizing the afferent branches of the trigeminal nerve [14].

However, Ibrahim and Shabana (2017) found no significant difference in OCR between the patients received sub‑Tenon's anesthesia with 2.5% bupivacaine (0.08 ml/kg), IV paracetamol (20 mg/kg), or a paracetamol rectal suppository (40 mg/kg) [15]. It may be that sub‑Tenon's anesthesia, unlike PBB, was not effective in blocking the nerve supply of EOM and preventing OCR.

In 2012, the American Society of Anesthesiologists Task Force on Acute Pain Management stated that "aggressive and proactive pain management is necessary to overcome pain in children, and regional blockade with local anesthetics should always be considered wherever possible" [16].

Our results showed that PBB is effective in controlling postoperative pain as it decreased the VAS score postoperatively at all times measured. Also, Deb *et al.*, (2001) showed that children in the block group had lower postoperative pain scores at all times [11].

Ghali *et al.*, (2001) found that PBB in vitreoretinal surgery provided more effective postoperative analgesia with lower diclofenac consumption and fewer patients requiring rescue analgesia [13].

Makkar *et al.*, (2018) found that PBB in children undergoing strabismus surgery, under desflurane anesthesia, was associated with reduced incidence of emergence agitation and OCR but did not significantly increase the time to the first analgesic [17].

5. Conclusion

PBB has a great benefit when combined with general anesthesia in strabismus surgery, as it reduced the incidence of OCR, postoperative pain score and PONV.

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Ethical Approval Statement: The protocol was approved by the local institutional ethics committee of Fayoum University Hospital Protocol Record M427. The study was performed on seventy (70) patients undergoing strabismus surgery. The study

was a prospective, randomized, parallel groups, controlled clinical trial.

Informed Consent Statement: A detailed informed consent had been signed by the eligible participants before recruitment and randomization.

Clinical Trial registration: Current Controlled Trials NCT04549844, Actual Study Start Date: August 14, 2019, Registration date: September 16, 2020, retrospectively registered, Retrieved from:

https://www.clinicaltrials.gov/ct2/show/NCT04549844

Conflicts of Interest: All authors declare no conflict of interest.

Availability of data and material: the datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Authors' contributions: M.R.A. (corresponding author) followed up the patients, collected the data, and performed the analysis revised the literature, and critically reviewed the manuscript. M.Y.A. followed up the patients, and wrote the manuscript. K.G.A. designed the study, revised the literature, and performed the analysis. M.L.B. revised the literature, performed the analysis, and critically reviewed the manuscript. All authors approved the final version of the manuscript.

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