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ORIGINAL RESEARCH ANESTHESIA FOR EYE SURGERY

Comparing a single injection peribulbar block with articaine 4% vs lidocaine 2% vs mepivacaine 3% for prevention of oculocardiac reflex in children undergoing strabismus surgery under general anesthesia: a randomized clinical trial

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ABSTRACT

Background & objective: Peribulbar block is used to prevent oculocardiac reflex (OCR) in children in addition to general anesthesia (GA). We compared GA with a single peribulbar block using articaine 4%, lidocaine 2%, or mepivacaine 3% for the prevention of the oculocardiac reflex (OCR) in children undergoing strabismus surgery.

Methodology: Fifty-five patients (7-14 years, both sexes) scheduled for strabismus surgery were enrolled in this randomized clinical trial. The sample size was calculated using Epi-info software, based on the following considerations: power at 80%, confidence limit at 10%, and alpha error at 5%. All received GA and a peribulbar block, divided as follows: Group A (n = 19): 5 mL articaine 4% with 1:100,000 adrenaline and 10 IU hyaluronidase; Group L (n = 18): 5 mL lidocaine 2% with 10 IU hyaluronidase; and Group M (n = 18): 5 mL mepivacaine 3% with 10 IU hyaluronidase. Continuous intraoperative monitoring (electrocardiography, pulse oximetry, capnography) was done, and Ringer's lactate was used for adequate hydration. Postoperative nausea and vomiting (PONV) were prevented with intravenous granisetron (0.01 mg/kg). The primary outcome of the study was the prevention of the OCR. The secondary outcomes were postoperative pain, PONV, Aldrete scores, and surgeon satisfaction.

Results: The Articaine group had the lowest occurrence of NSAID use, postoperative nausea and vomiting, subconjunctival hemorrhage, atropine use, as well as the surgeon stop request. In addition, the lidocaine group had the lowest number of positive VAS. Moreover, OCR episodes were the lowest among Group A. Only a single episode occurred in a single person. This is compared to 4 and 3 patients affected in the Groups L and M, respectively. On the other hand, Group A reported the highest number of shifted eyes (3) in comparison with 2 and 1 in Groups L and M, respectively. For ballooning, Group L had the lowest occurrence with a single event compared with 2 events in the other two groups, without a substantial difference ($P > 0.05$).

Conclusions: Articaine 4% was the most effective in reducing the incidence of the OCR and improving both intraoperative and postoperative outcomes in pediatric strabismus surgery.

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Abbreviations: HA: hyaluronic acid. LA: Local anesthetics, OCR: oculocardiac reflex

Keywords: Articaine; Lidocaine; Mepivacaine; Oculocardiac Reflex; Strabismus Surgery

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1. INTRODUCTION

Strabismus is a common childhood health problem.[1] The OCR arc has afferent and efferent limbs: the trigeminal nerve is the sensory afferent, and the vagus nerve is the efferent.[2] Strabismus surgery cases are at high risk for the potentially life-threatening OCR. Key preventive measures like adequate anesthetic depth and anticholinergics do not fully eliminate this risk with routine prophylaxis.[3]

OCR incidence in strabismus surgery varies with premedication and anesthetics.[4] Additionally, extraocular muscle manipulation is correlated with increased postoperative nausea and vomiting (PONV).[5,6]

Articaine 4% is an intermediate-potency, short-acting amide local anesthetic with rapid ester metabolism, effective for dental and regional blocks (spinal, epidural, ocular, intravenous).[7] For ocular akinesia, it's safer and superior to lidocaine 2%/levobupivacaine 0.5%, with a faster onset than lidocaine 2%.[8,9]

Mepivacaine's local anesthetic profile is like lidocaine's, providing a rapid-onset, moderate-duration, profound nerve block. Unlike lidocaine, mepivacaine has less vasodilator activity, leading to a slightly longer duration.[10] Clinically, lidocaine, an amide local anesthetic with an intermediate duration of action, provides a rapid onset of its local anesthetic effects.[11]

Hyaluronidase, an enzyme that degrades hyaluronan, also called hyaluronic acid (HA), enhances the dispersion/absorption of drugs and fluids, facilitating rapid anesthetic penetration, even in difficult-to-access areas. Its ophthalmic use began in 1949 when Atkinson added it to retrobulbar and lid blocks.[12]

This study compared the effects of articaine 4%, mepivacaine 3%, and lidocaine 2% on OCR incidence and postoperative analgesia, aiming to decrease OCR occurrence.

2. METHODOLOGY

This randomized clinical trial recruited 55 patients, aged 7 to 14 years, of both sexes, and with American Society of Anesthesiologists (ASA) physical status I or II, who were scheduled for strabismus surgery. Conducted from February 2022 to February 2023, the study received approval from the Ethical Committee, Cairo University Hospitals, Cairo, Egypt (approval code: MD-397-2021), and informed written consent was obtained from patients' relatives. Exclusion criteria encompassed patients with ASA III or IV status, endophthalmitis, orbital fractures, congenital or cardiac anomalies, local anesthetic allergies, revision surgeries, and surgeon refusal.

The sample size was calculated based on the following considerations: power at 80%, confidence limit at 10%, and alpha error at 5%.

Cases were allocated into three groups by an independent anesthesia staff member who wasn't related to the study. Patients allocated to the groups were given a closed envelope containing a card with their group number and identification, which was opened only after arrival in the operating room. All patients received general anesthesia and a peribulbar block: Group A (n = 19) with 5 mL articaine 4% + 1:100,000 adrenaline + 10 IU hyaluronidase; Group L (n = 18) with 5 mL lidocaine 2% + 10 IU hyaluronidase; and Group M (n = 18) with 5 mL mepivacaine 3% + 10 IU hyaluronidase.

After receiving a preoperative intravenous sedative of midazolam 0.05 mg/kg upon operating room arrival, standard monitoring (ECG, non-invasive blood pressure, pulse oximeter) was initiated. Intravenous induction of anesthesia was then performed, followed by the insertion of a 24–22 G IV catheter and an appropriately sized laryngeal mask airway (LMA). Anesthesia was maintained with 100% oxygen and sevoflurane, with spontaneous respiration and continuous end-tidal carbon dioxide ($EtCO_2$) monitoring via capnography.

For Group A:

GA was induced as previously described, and a peribulbar block of up to 5 mL (according to ocular volume) of articaine 4% with 1:100,000 adrenaline mixed with 10 IU of hyaluronidase was administered using a single injection technique. A 26/27-gauge needle was inserted as far laterally as possible in the

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Table 1: Patients' characteristics of the studied groups

Variables		Articaine Group (n = 19)	Lidocaine Group (n = 18)	Mepivacaine Group (n = 18)	P
Age (Years)		9.00 (8.00-11.50)	10.00 (9.00-11.75)	10.00 (8.25-11.75)	> 0.9
Gender	**Female**	10 (53)	11 (61)	8 (44)	0.6
	Male	9 (47)	7 (39)	10 (56)	
Duration of surgery (mins)		60 (40-65)	42(35-60)	45(32-88)	0.6

Data are presented as median (IQR) or frequency (%);

inferotemporal quadrant. Once under the globe, the needle was directed along the orbital floor, passing the globe equator to a depth controlled by observing the needle/hub junction reaching the plane of the iris. After negative aspiration for blood, with the globe in primary gaze, injection was started, and the injected volume was guided by digital intraocular pressure.

For Group L:

After the standard general anesthesia induction, a single peribulbar injection of up to 5 mL (volume adjusted to the eye) of lidocaine 2% with 10 IU of hyaluronidase was administered.

For Group M:

Subsequent to the standard general anesthesia induction, a single peribulbar injection of up to 5 mL (volume adjusted to the eye) of mepivacaine 3% with 10 IU of hyaluronidase was administered.

Throughout the surgery for all three groups, patients underwent continuous intraoperative monitoring (electrocardiography, pulse oximetry, capnography) and received intravenous Ringer's lactate for adequate hydration until oral intake was possible. The incidence of the OCR was assessed within 2-3 min following anesthesia induction and peribulbar block, and the duration of surgical preparation. Intraoperative OCR monitoring was also conducted during eye manipulations, with careful attention to anesthetic depth and hemodynamic stability (heart rate, blood pressure). Intraoperative analgesia was provided via intravenous fentanyl (1 µg/kg), and postoperative vomiting was prevented with intravenous granisetron (0.01 mg/kg). Intraoperative mean arterial blood pressure and heart rate were recorded at induction, incision, and every 5 min until procedure completion. Any occurrence of OCR was documented, noting its onset, timing, potential surgical triggers, and the therapeutic interventions (medications, additional blocks) employed to manage it.

A heart rate decrease of more than 20% from baseline prompted the surgeon to cease the procedure, and if ineffective, an intravenous atropine dose of 0.01 mg/kg was administered, with the dosage documented. Postoperatively, patients were transferred to the PACU for about 2 hours of observation before ward discharge, with assessments immediately post-discharge and every 15 min thereafter for a total of 6 hours. Postoperative recovery was evaluated via the Aldrete score, and pain was assessed every 15 min using the VAS scale. Documented postoperative pain was routinely managed with paracetamol (15 mg/kg every 6-8 hours), with additional analgesics (e.g., NSAIDs) administered and recorded for VAS scores above 3. Persistent postoperative vomiting was treated with appropriate antiemetics, and any occurrences were noted. Any peribulbar block-related complications, such as hemorrhage and hematoma, were also recorded.

The primary outcome of the study was the prevention of the OCR. The secondary outcomes were postoperative pain, PONV, Aldrete scores, and surgeon satisfaction.

2.1. Sample size calculation

The sample size calculation was performed using EpI-Info 2002 software statistical package designed by the World Health Organization (WHO) and by the Centers for Disease Control and Prevention (CDC). The sample size was calculated based on the following considerations: power at 80%, confidence limit at 10%, and alpha error at 5%. The sample size calculation was informed by a 13% prevalence of the OCR in peribulbar block cases, as reported in the study by Gupta et al. [13]. Nine cases were added to the dropout. Therefore, we recruited 55 cases.

2.2. Statistical analysis

SPSS v27 (IBM©, Chicago, IL, USA) was used for data analysis. Normality was checked by Shapiro-Wilks and histograms. Parametric quantitative data (mean ± SD) were analyzed by ANOVA (Tukey post hoc); non-parametric (median IQR]) by Kruskal-Wallis (Mann-Whitney post hoc). Qualitative data (frequency,

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Table 2: Primary and secondary outcomes of the studied groups

Parameters		Articaine Group (n = 19)	Lidocaine Group (n = 18)	Mepivacaine Group (n = 18)	P
Surgeon satisfaction		10.0(6.0-10.0)	10.0(5.25-10.0)	9.0(7.25-10.0)	0.5
NSAID use		2(11.0)	7(39.0)	6(33.0)	0.12
VAS scale	**Negative**	17(89.0)	11(61.0)	12(67.0%)	0.12
	Positive	2(11.0)	7(39.0)	6(33.0%)	
Aldrete score		10.0(9.0-10.0)	9.0(9.0- 10.0)	10.0(9.0-10.0)	0.8
PONV		2(11.0)	3(17.0)	4(22.0)	0.6
Balloning		2(11.0)	1(5.6)	2(11.0)	> 0.9
Subconjunctival hemorrhage		2(11.0)	3(17.0)	3(17.0)	0.8
Shifted eye		3(16.0)	2(11.0)	1(5.6)	0.9
Atropine use		1(5.3)	4(22.0)	2(11.0)	0.3
Surgeon asked to stop		1(5.3)	3(17.0)	3(17.0)	0.5
OCR episodes	**0**	18(95.0)	14(78.0)	15(83.0)	0.6
	1	1(5.3)	2(11.0)	2(11.0)	
	2	0(0.0)	2(11.0)	1(5.6)	

Data are presented as median (IQR) or frequency (%). 2Kruskal-Wallis rank sum test; Fisher's exact test, OCR: oculocardiac reflex; P < 0.05 considered as significant; PONV: Post-operative nausea and vomiting

percentage) were analyzed by Chi-square. Significance was P < 0.05 (two-tailed).

3. RESULTS

Of 74 assessed patients, 11 were ineligible and 3 refused, leaving 60 randomized into three groups of 20. Five patients dropped out (1 patient suffered from perforation, 2 patients suffered from hematoma of the eyelid, and two patients suffered from a cut in the rectus muscle), resulting in 55 patients for statistical analysis.

The demographic data of the patients and the surgery are given in Table 1. Patients' characteristics were insignificantly different between the groups.

VAS scale was 2 (11%) patients, 7 (39%) patients, and 6 (33%) patients in Groups A, L, and M, respectively. The median (IQR) value of the Aldrete score was 10 (9-10), 9 (9-10), and 10 (9-10) in Groups A, L, and M, respectively.

The complications noted in the three groups, including PONV, ballooning, subconjunctival hemorrhage, bradycardia requiring atropine, and shifted eye, are presented in Table 2. Patients asked the surgeon to stop in Groups A, L, and M, respectively. OCR episodes were 0 in 18 (95.0%) patients, 14 (78.0%) patients, and 15 (83.0%) patients in Group A, Group L, and Group M, respectively. OCR episodes were 1 in 1(5.3%) patients, 2 (11.0%) patients, and 2 (11.0%) patients in Group A, Group L Group M, respectively. OCR episodes were 2 in 0 (0%) patients, 2 (11.0%) patients and 1 (5.6%) patient in Group A, Group L Group M, respectively. The Group A group had the lowest occurrence of NSAID use, postoperative nausea and vomiting, subconjunctival haemorrhage, atropine use as well as the surgeon stop request. In addition, the Group L patients had the lowest number of positive VAS scores. Moreover, the OCR episodes were the lowest among Group A. Only a single episode occurred in a single person. This is compared to 4 and 3 patients affected in the Groups L and M, respectively. On the other hand, Group A reported the highest number of shifted eyes (3) in comparison with 2 and 1 in Group L and Group M, respectively. For ballooning, Group L had the lowest occurrence with a single event in comparison with 2 events in the other two groups, without a substantial difference (Table 2).

4. DISCUSSION

This study primarily aims to prevent and attenuate the OCR in children (7-14 years) undergoing strabismus surgery.

The use of a peribulbar block with lidocaine 2% in young patients has been described in several studies.[6,13,14-21] In

our study, the total number of patients who received a peribulbar block using the lidocaine mixture was 18, and they were allocated to Group L. In our study, 2 patients out of 18 experienced the OCR during the operation,

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which represents 11% of the total group. The efficacy of the peribulbar block with lidocaine 2% was described in other studies.

We observed the OCR in 4 patients, a rate that bears a slight resemblance to the 13% reported.[13] Conversely, some researchers found a lower OCR incidence, with the added benefit of a rapid block onset (3 ± 5 min) and analgesia achieved by the time of surgical preparation.[15,18] Other researchers even documented a complete absence of OCR in their peribulbar group, a substantial divergence from our results.[20-22]

We recorded the complications encountered in our study. The surgery had to stop in 3 (17%) cases; booster atropine dosage was given in 4 (22%) patients. Other complications noted were: subconjunctival hemorrhage, a shifted eye, conjunctival ballooning, and PONV. Various authors have given different statistics of the complications, from no complications to minor complications.

Surgeon satisfaction was expressed as median 10 (5.25, 10.00) (P = 0.5). In Deb K, et al. study,[15] peribulbar block seems a safe, useful analgesic for pediatric eye surgery. In Gupta N, et al.[13] study peribulbar block showed no serious complications. Various researchers were of the opinion that peribulbar anesthesia is safe with only minor complications.[17-23]

In our study, 7 patients in Group L encountered postoperative pain, which represents 39% of the total group, and 11 patients were pain-free, which represents about 61% of the total group. NSAIDS were used in 7 (39%) patients of the group L (P = 0.12). A similar incidence of postoperative pain was observed by other researchers including Deb et al. and Darwish A.[13,15-18] Subhedar et al. reported 3/17 patients who suffered from pain/emesis (PONV).[22] Most studies suggest the lidocaine peribulbar block isn't fully effective against postoperative pain.

Peribulbar block with Articaine 4% was used in 19 patients. The median duration was 60 (40−65) min. The incidence of OCR was one case (5.3%) of the total group. No intervention was needed in 18 cases, which represented 95% of the group. The surgeon was asked to stop in only one case. The need for NSAIDS was in 2 (17%) (P = 0.12). Median Aldrete score was 10.00 (9.00−10.00) (P = 0.8). PONV was encountered in 2 cases, and injection complications were also encountered in 2 cases of ballooning and hemorrhage, and 3 cases encountered a shifted eye (P = 0.9). In Ripart J et al. (1998) in their study proved that articaine was superior to a standard mixture of 0.5% bupivacaine and 2% lidocaine for peribulbar anesthesia. However, there may be a need for supplementary dosage. Articaine provided a longer period of analgesic effect compared to mepivacaine.

In our study, mepivacaine was used in 18 cases (Group M). Median age was 10.00 (8.25, 11.75). The male: female ratio was 8 (44%). The medical duration of surgery was 45 mins (32,88). OCR was encountered in 3 cases in this group. Median Aldrete score was 10.00 (9.00, 10.00). PONV was encountered in 4 (22%) cases. Postoperative pain was seen in 6 (33%) patients. No pain was noted in 12 cases of the group.

Total injection complications were: 2 ballooning, 3 hemorrhages, and one with a shifted eye (P = 0.9). The surgeon was asked to stop in three cases, and a booster atropine dose was given to 2 patients. Ripart J et al. (1998) no complications were noted.[27] In Oel et al. (2014) study, mepivacaine was only effective in 50% of the cases compared with etidocaine regarding postoperative analgesia.[28] Cardiac arrhythmias were noted in the Group-M in Luchetti et al. (2000) study.[29]

5. LIMITATIONS

A limitation of this study is the relatively modest sample size, which may impact the generalizability of the findings, particularly given its single-center design.

6. CONCLUSION

Among the three local anesthetics evaluated, articaine 4% was the most effective in reducing the incidence of the OCR and improving both intraoperative and postoperative outcomes in pediatric strabismus surgery. Articaine was associated with the lowest rates of OCR episodes, atropine use, surgeon stop requests, PONV, and NSAID requirement. While lidocaine 2% showed the lowest number of patients reporting postoperative pain on the VAS, and mepivacaine 3% performed comparably in certain aspects, articaine offered the best overall profile in terms of intraoperative stability and postoperative recovery. Articaine may be the preferred agent for PBB in pediatric strabismus procedures.

7. Data availability

The numerical data generated during this research are available from the authors.

8. Conflict of interest

All authors declare that there was no conflict of interest.

9. Funding

The study utilized the hospital resources only, and no external or industry funding was involved.

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10. Authors' contribution

ASS and AZM: Development of the protocol, data collection.

HBE and HAEN: Original idea and the protocol, collected and analyzed data, manuscript drafting, and guarantor.

AF and HAEN: Prepared the manuscript.

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