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CLINICAL RESEARCH

Minimum effective volume of local anesthetic in peribulbar block: does it differ with the eyeball axial length?

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Abstract
Background: Peribulbar Anesthesia (PBA) is a relatively safe method for cataract surgery. The anesthetic volume should be adjusted according to the axial eyeball length. Thus, using Minimum Effective Volume (MEV) of local anesthetic helps avoiding unnecessary volumes, preventing increases in intra-ocular pressure, and producing satisfactory conditions for cataract surgery. This study aims to determine the MEV90 of local anesthetics in relation to eye globe axial length in peribulbar blocks for cataract surgery.
Methods: Patients scheduled for cataract extraction under local anesthesia were divided according to their axial eyeball length; Group 1 included those with axial length from 22 to 24 mm, Group 2 included patients with axial length from 24.1 to 26 mm. The initial volume used was 7 mL of a solution of bupivacaine 0.5% (3 mL) + lidocaine 2% (3 mL) + hyaluronidase 150 IU (1 mL). The subsequent volumes were dependent on the response of the previous patient, by using a Bias Coin Design (BCD) and Up and Down Method (UDM) for MEV-90 determination.
Results: The study was concluded with 119 patients. Sixteen patients needed supplemental volume of local anesthetic in Group 1 and thirteen in Group 2. The MEV90 for Group 1 was approximately 5.82 mL (95% CI 5.6 to 5.87 mL) and 5.45 mL for Group 2 (95% CI 5.38 to 5.91 mL). No major complications were noted. There was a negative correlation between the effective volume of LA and eye globe axial length in both groups ($p = 0.001$).
Conclusion: The MEV90 of local anesthetics for peribulbar block show a strong and inverse correlation with eye globe axial length. This may help achieving an effective block with minimum complications.

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Background

The peribulbar block is the most common regional anesthetic technique used worldwide to provide anesthesia for the cataract extraction and intraocular lens Implantation.[1] It is a relatively safe procedure when performed by well-trained staff, particularly whenever contrasted with retrobulbar block, which is related to devastating and potentially life-threatening complications.[2]

Most patients scheduled for ophthalmic surgery are elderly and have chronic medical problems. Local anesthesia, unless contraindicated, is the technique of choice as it is associated with the minimum morbidity and minimum disturbance of the patient's daily activity.[3]

Day case intraocular surgery under local anesthesia has great economic value and is generally the best option. Peribulbar Anesthesia (PBA) for intraocular surgery by single-injection technique is a simple and satisfactory alternative approach for ocular regional anesthesia. A solitary, instead of different penetrates technique, offers impressive favorable circumstances, for example, satisfactory absence of pain, diminished local anesthetic volumes, site of the puncture in relatively avascular region, and more precise needle way.[4]

Lidocaine hydrochloride 2% is the most commonly used injectable agent for local anesthesia. The onset of action is within 1 minute and can last 1–3 hours. Bupivacaine hydrochloride 0.5–0.75% is a longer-acting agent with a duration of 6–8 hours. In contrast to lidocaine, bupivacaine has a slower onset of action of 10 minutes but can be used in combination with the previous.

The use of hyaluronidase as a coadjutant to local anesthesia is well established in ophthalmic surgeries. It gives a superior dispersion of local anesthetic around the orbit and utilization of lower volumes.[5]

Also, the volume of local anesthetic utilized in the peribulbar block is a significant factor identified with an ascent in intraocular pressure (IOP). Other factors, for example, variation in orbital volume and tightness of orbital septum, may also assume a part.[6]

The optimal minimum effective volume (MEV) calculated effective volume of local anesthetic which result in a successful lock in 90% of patients remains to be a subject in discussion and lacks proper knowledge in current literatures. This is a relevant issue to avoid IOP increase and produce satisfactory conditions for cataract surgery.[7]

The aim of this study was to determine MEV90 of local anesthetic, according to eye globe axial length, in peribulbar block for cataract surgery.

Methods

This prospective double-blind research was conducted between July and December 2019, in Ain Shams University Hospital. The study was registered in Clinical Trials (clinicaltrials.gov) (ref: NCT04036201). Upon Ethical Committee approval, on July 2019, and written informed consent of all patients, the study enrolled adult patients of ages between 40–70 years, of both gender, American Society of Anesthesiologists (ASA) physical status I, II, and III scheduled for elective cataract surgery using phacoemulsification method with intraocular lens implantation operation.

Exclusion criteria included patients' refusal or allergy to local anesthesia, patients with a single eye, high myopes (axial length >26 mm), those with ocular infection, complicated vitreous hemorrhage, or associated glaucoma. Also, patients who had any systemic contraindications (as severe hypertension) were excluded. Figure 1 represents a flowchart illustrating the number of patients who accepted to participate, and those who were excluded or dropped out of the study.

All patients were submitted to eye globe axial length ultrasound (US) evaluation with Mindray M5 (Shenzhen Mindray Bio-Medical Electronics Co., LTD. Shenzhen, China). Using a high frequency linear array transducer (10 MHz), the patient was examined in supine position, closed eyelid, and asked to maintain a straightforward gaze. A light touch of the transducer to the eyelid, using US gel, was applied, avoiding additional pressure to the cornea, which may alter axial diameter. With image of eye globe centered on the screen, gain and depth were adjusted. The measurement was taken from median point of the cornea, anteriorly, to the sclera, posteriorly. Following this, patients were assigned to either of two groups according to their eye globe axial length.

Group 1 (patients with axial length amongst 22 and 24 mm) and Group 2 (patients with axial length amongst 24.1 and 26 mm). All patients were given a combination of bupivacaine 0.5% (3 mL) + lidocaine 2% (3 mL) + hyaluronidase 150 IU (1 mL) to an overall volume of 7 mL as the starting volume.

Patients were transferred to the operating theatre fasting for eight hours. Peripheral intravenous (IV) cannulation was performed, and basic monitoring was applied and documented, involving heart rate (HR), electrocardiogram (5 leads), arterial blood pressure, and Oxygen Saturation (SpaO2). Supplementary oxygen was provided during the operation at 3 $L.min^{-1}$. Sedation with IV propofol 0.5 $mg.kg^{-1}$ and topical anesthesia using tetracaine 0.5% was applied to all patients' eyes.

The local anesthetic mixtures were arranged at bedside before the injection, stored in an identified closed container and given to the patient by a physician not directly involved in the research.

All peribulbar blocks were performed by two anesthesiologists with solid expertise in ophthalmic anesthesia. As a double-blinded study, anesthesiologists had no knowledge of study groups, and subjects were unaware to what LA volume was given. The anesthesia provider was responsible for assessment of response to the block. For the peribulbar block, a single injection was performed, with a 25G 16-mm cutting bevel needle. With the eye fixed in primary gaze position, the insertion location was percutaneous in the lower edge of the orbit 0.5 cm below and in line with the inferior lacrimal punctum. The needle was progressed in an anteroposterior course for half of its distance and then diagonally along the course of the optical foramen toward the Angie between nose and eyebrow. After negative aspiration, the allocated volume of local anesthetic solution was slowly injected for 30 to 40 seconds, until observing full drop of upper eyelid, as described by Rizzo et al.[2] A gentle orbital massage was then applied for 2 minutes.

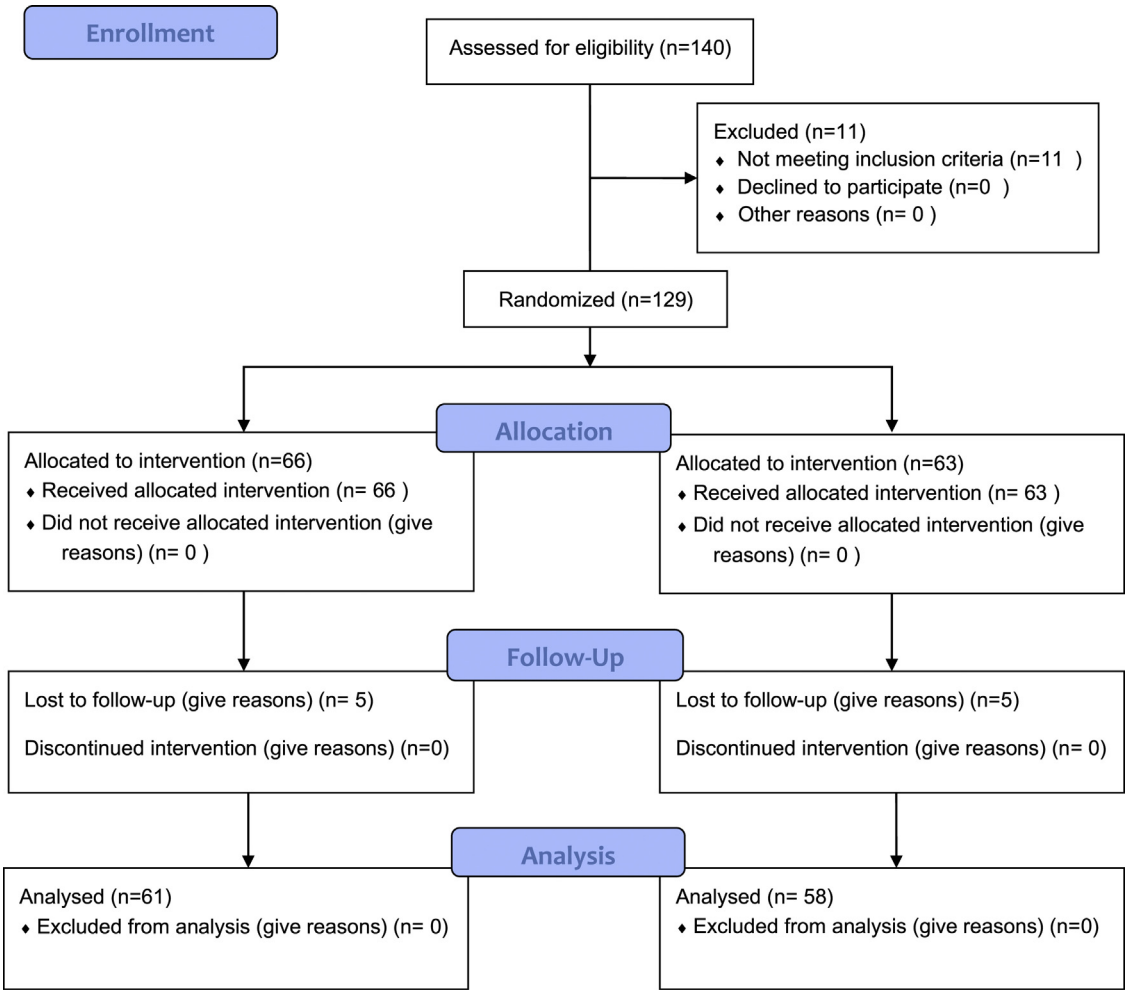

Figure 1 CONSORT flowchart for the details of the study conduct.

The starting volume of local anesthetic was 7 mL, and subsequent volumes were given based on the response of the previous patient. In case of failure, the following subject received a greater volume (described as the prior volume with the addition of 0.1 mL). Upon a successful response, the subsequent patient was randomized to a lower volume, which equaled to the prior volume with a decrease of 0.1 mL, with a probability of 11%, or the same volume, with the probability of 89%.[8]

Global anesthesia (feeling pain on touch) was evaluated on a 0–2 scale where 0 = no anesthesia, 1 = partial but satisfactory anesthesia, and 2 = complete anesthesia.

Motor block was assessed by estimation of globe akinesia in the four quadrants, discriminated by the 4 directions of the gaze: lateral, medial, superior, and inferior. A 3-point scoring method was chosen, in which 0 = akinesia, 1 = incomplete akinesia, and 2 = natural movement, with a total score ranging from 0–8 for the four muscles.

Additional blocks were given when akinesia and anesthesia were inadequate 10 minutes after injection, and the response was considered a failure.

The point in time to satisfactory surgical anesthesia was observed also as the need for additional anesthesia. The pain was evaluated by straightforward questioning using a 3-point scoring method (no pain = 0, discomfort = 1, pain = 2) during the procedure.

Stage of chemosis and subconjunctival hemorrhage were noted after 10 minutes. Minor adverse events, such as coughing, vomiting, hypotension, bradycardia, tachycardia, arrhythmias, proptosis, were also documented and managed accordingly Any major problems, such as globe puncture or retrobulbar hemorrhage were also observed and if any, anesthesia should be canceled, and the operation rescheduled.

Statistical analysis

The decision to use 7 mL as initial volume of local anesthetic was made upon our routine clinical practice and guided by previous studies.[2,11,25] The amount provided to the next patient varies according to the response of the prior one.

Isotonic regression was used to verify the MEV90 with bias-adjusted 95% Confidence Interval (CI) obtained by bootstrapping; 3000 bootstrap samples were used to calculate the mean value of the estimate.

The sample size was estimated following the method of Durham et al.,[9] for whom the maintenance of estimated parameters would be achieved with a minimum of 40 subjects. This assumption was made upon simulations

Table 1 Descriptive analysis of data related to the 2 groups.

	Group 1 (22–24 mm)	Group 2 (24.01–26 mm)	*p*-value
Total number	61	58	
Age (years)	51.1 ± 3.3	50.9 ± 2.56	0.551
Male patients	35(57)	37(64)	0.474
BMI	27.15 ± 1.61	26.9 ± 1.43	0.922
ASA (I/II/III)	30/22/9	28/24/6	0.712
Failure responses	16(26)	13(22)	0.628
Duration of surgery (min)	31.1 ± 1.39	30.9 ± 1.16	0.503

Data presented as frequency or count (%) or mean ± SD.

for various circumstances of dose allocation, sample amount and several positive responses. Accordingly, since the possibility of receiving a lesser volume after a successful response in the prior patient is 11%, the minimum sample size would be the lowest manifold of 9 above 40, which is 45. Thus, we resumed enrolling patients until 45 successful responses were achieved for each group, at which point the study was considered finalized.

Statistical analysis was performed using the R statistical software package (R Foundation for Statistical Computing, Vienna, Austria [ISBN 3-900051-07-0; http://www.R-project.org]) and Microsoft® Excel 2010 (Microsoft, Seattle, WA, USA). Continuous variables are shown as mean Standard Deviation (SD) or median (range), while categorical variables are presented as frequency.

Results

The 45 successful responses in each group were achieved after enrolling 61 patients in Group 1 and 58 patients in Group 2. Therefore, the research was concluded with 119 patients. The details of the study conduction are presented in Figure 1. Demographic records are demonstrated in Table 1. All patients with successful responses had uneventful operations. The number of patients who required supplemental volume of local anesthetic was 16 in Group 1 and 13 in Group 2. The response of each patient in Groups 1 and 2 is demonstrated by Figures 2 and 3 respectively.

The MEV90 for Group 1 was nearly 5.82 mL (95% CI 5.6–5.87 mL) and 5.45 mL for Group 2 (95% CI 5.38–5.91 mL). The MEV90 and their confidence intervals for each group are explained in Figures 2 and 3, respectively. Table 2 presents the volumes given in each group., the MEV-90, and their confidence intervals. In both groups, there were statistically significant strong negative correlations between the axial length of the eye globe and the local anesthetic volume in cases of successful responses as demonstrated in Figure 3. The frequency of minor complications is shown, with no significant variations between both groups ($p = 0.676$). No major complications were observed in any of the patients.

Discussion

The purpose of this study is to determine the minimum effective volume (MEV90) of the local anesthetic in two groups of patients with different eyeball axial lengths determined by ultrasound-guided examination of the eye globe. A correlation between axial length and dose-response in cataract surgery is verified by our results.

Interesting research hinted that patient favor Peribulbar Block (PBA) to topical anesthesia for cataract operation.[10] Ahmed S et al., concluded that a Percaruncular single injection peribulbar anesthesia for phacoemulsification in patients with axial myopia is an effective and relatively safe technique.[11]

There are significant variations in orbit and globe sizes among the population which lead to significant differences in potential intra- orbital space volume available for local anesthetics. The size of the human adult eye is varies between 22 and 24.8 mm (axial) and between 21 and 27 mm in the transverse diameter.

The axial length, which is described as the distance from corneal apex to an interference peak corresponding to retinal pigment epithelium or Burch's membrane, may differ in certain conditions, such as myopia and hypermetropia. The ultrasonic measurement of axial length in advanced cataract situation was confirmed by Goyal et al., with a variation of 20 to 26 mm.[14]

The relevance of this is because axial lengths greater than 26 mm are present in myopic eyes and carry a risk of eye globe perforation of 1:140 needle blocks performed.[12–15]

Clinically relevant predictors of the required amount of local anesthetic to provide reasonable akinesia and anesthesia are yet to be established. Volumes from 6 to 10 mL are usually part of clinical practice. Hence achieving an optimal injected volume is of utmost importance, once insufficient volumes can lead to inadequate blocks, and excessive volumes can cause a hazardous increase in IOP. On another hand, IOP rise relates to oculo-cardiac reflex, vitreous prolapse and acute ischemic optic neuropathy. This justifies the need to detect a minimum effective volume.[16]

An excessive rise in intraocular pressure can lead to oculocardiac reflex, vitreous prolapse and acute ischemic optic neuropathy That is why researchers have made every effort to detect minimum effective volume required.[17]

A variety of techniques have been used to determine the adequate amount of local anesthetic injected for each case. Miranda et al. conducted a prospective, study on 51 patients scheduled for cataract surgery to evaluate total upper eyelid drop as a new endpoint for a single injection peribulbar block. Applying this procedure, adequate ocular akinesia was accomplished in 90% of eyes 10 minutes following injection. The mean volume of the local anesthetic mixture injected was 9.1 mL.[18]

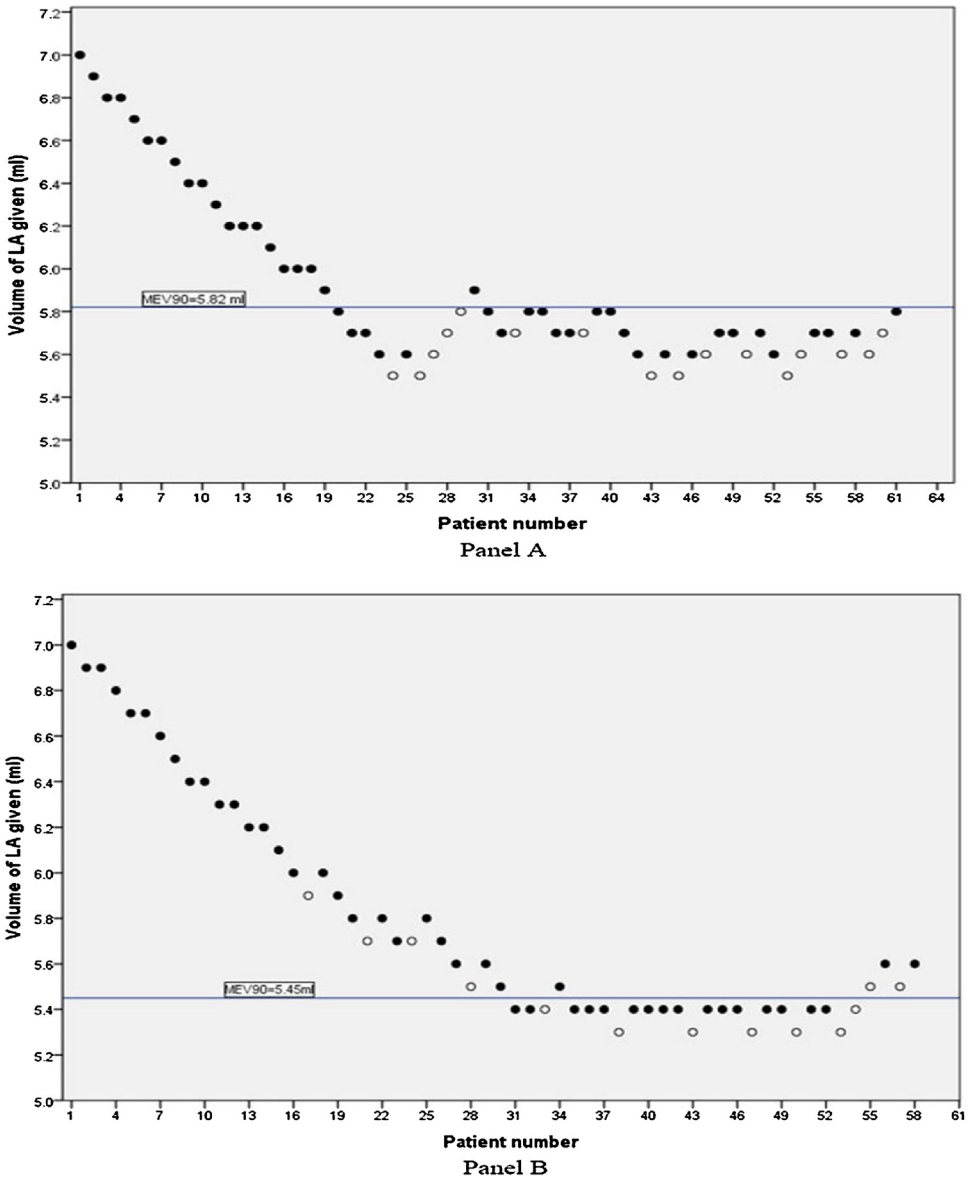

Figure 2 Patients' responses in Group 1 (Panel A) and in Group 2 (Panel B) to different volumes given, the reference line indicates the MEV90. Response to LA volumes ●Success ◯ Failure; LA, Local Anesthetic; MEV90, Minimum effective volume of local anesthetic to 90% successful response.

Table 2 Analysis of volumes of local anesthetic and MEV-90 for each group.

	Group 1 (22–24 mm)	Group 2 (24.01–26 mm)	*p*-value
Volume given (mL)	5.89 ± 0.39	5.78 ± 0.49	0.175
Median (range)	5.7 (5.5–7)	5.6 (5.3–7)	0.487
MEV-90 (mL)	5.82 ± 0.23	5.45 ± 0.22	N/A
95% CI of MEV90	5.61 to 5.87	5.38 to 5.91	

Data presented as mean ± SD.
CI, Confidence Interval.

To the best of our knowledge, the impact of the eye globe axial length on the volume of local anesthetics for peribulbar block still lacks grounding in current literature. Our data confirm a correlation between axial length and dose-response of cataract surgery, longer eyes were found to require a lower amount of local anesthetic This is supported by our results, showing that MEV90 for Group 1 (axial length between 22 and 24 mm) was nearly 5.82 mL and 5.45 mL for Group 2 (axial length between 24.1 and 26 mm). A reasonable hypothesis is that the distribution of the local

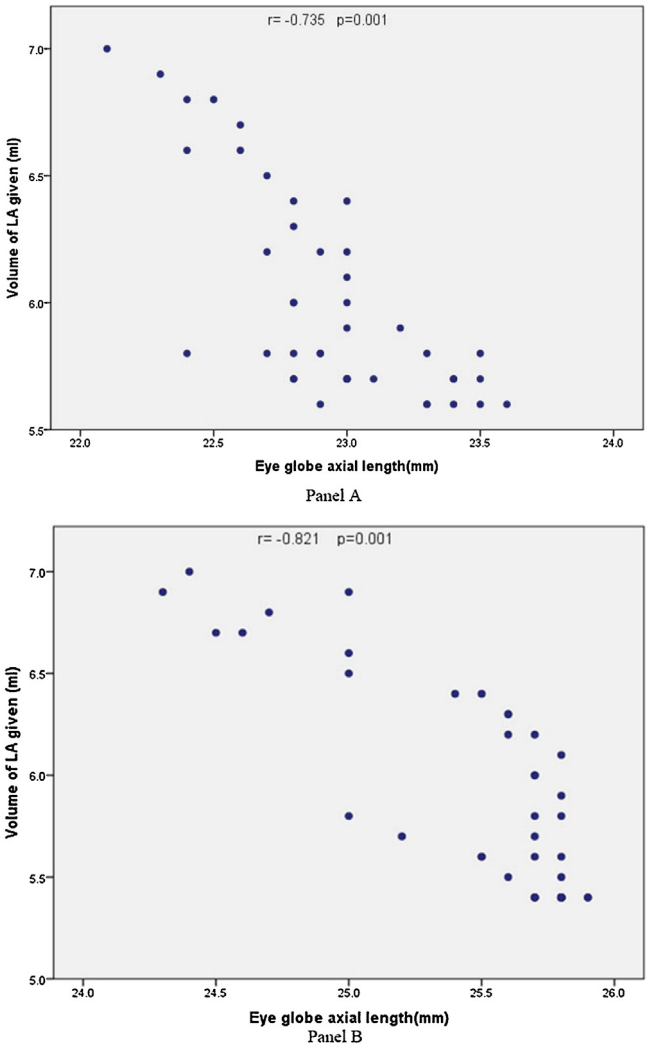

Figure 3 Correlation between the eye globe axial length and the volumes of LA given in cases of successful responses in Group 1 (Panel A) and in Group 2 (Panel B). The *p*-values indicates significant correlations. LA, Local Anesthetic.

anesthetic in a more compact space. Therefore, the potential intraorbital space to accommodate injected volume is decreased, justifying that a larger eye globe requires lower volumes.

In comparison to our results, Soares et al. found that the minimum anesthetic volumes of 0.5% racemic bupivacaine and 0.5% levobupivacaine, needed for retrobulbar extraconal anesthesia for patients undergoing cataract extraction, were 6 mL and 6.2 mL respectively where they use single-injection and inferior-lateral approach.[19]

On the other hand, Mostafa et al.[20] have shown substantial variations in previous studies designed for ocular blocks using different amounts of local anesthetics. in bulbar akinesia, relating a 4 ml volume of anesthetic solution, compared to 2.5 mL, with superior ocular akinesia, however, retrobulbar extraconal block guarantees local anesthetics beyond the eye equator, near to the cone, being altered from a peribulbar block where the needle is tangent to eye equator, Ripart et al. verified that a trivial volume of (PBA), injected local anesthetic (5–6.5 mL) is sufficient to encircle the eyeball and cause analgesia.[21] Cehajic K.J et al. confirmed that 4 mL of anesthetic provided via the sub-Tenon way is better than a single peribulbar injection to an equal volume.[22]

A biased coin design (BCD) was used to assess MEV90 of local anesthetics in the peribulbar block. BCD has been previously validated by prior studies to investigate MEV50 and MEV90 of local anesthetics in regional anesthesia[23] we used this same technique.[24]

Additionally, the findings point to clinical relevance of minimizing the volume of local anesthetics in the peribulbar block by using eye globe axial length measurement guided by ultrasound. This may contribute to add safety to the procedure and decrease complications such as a rise in IOP.

A limitation of this study is that we did not measure intraocular pressure during block administration and in the postoperative period to avoid handling the operated eye in the immediate postoperative period.

Conclusion

The MEV90 of local anesthetics for peribulbar block show a strong and inverse correlation with eye globe axial length. This may help achieving and effective block with minimum complications.

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We used the available resources of the Department of Anesthesiology, Faculty of Medicine, Ain Shams University.

It is registered with clinical trials.gov (ref: NCT04036201).

Conflicts of interest

The authors declare no conflicts of interest.

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