

A Prospective Study

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# **RESEARCH ARTICLE**

# Comparison of Two Needle Lengths in Regional Ophthalmic Anesthesia in the Medial Canthus Approach. A Prospective Study

Rehab S. Khattab<sup>1</sup>, Iman S. Aboul Fetouh<sup>1</sup>, Norhan A. Sherif <sup>1</sup>, Noha A. Osama<sup>1</sup>, Mayada K. Mohamad <sup>1</sup>, Nader N. Naguib<sup>2</sup>

# ABSTRACT

**Purpose:** To compare the efficacy and safety of using a short, fine needle to the standard needle in performing medial canthal peribulbar blockade. **Patients & Methods:** The study enrolled 110 patients who were randomized into two groups: group A in which a short, fine (12mm, 28G) needle was used to perform the block, and group B in which the standard (25mm, 24G) needle was used to perform the block. The needle was inserted into the medial canthus and was straight advanced to its full length and the local anesthetic solution was injected. Ocular akinesia was assessed after 3, 5, and 10 minutes using the simple akinesia score. If the block was inadequate for surgery after 10 minutes, supplementation. **Results:** No significant difference was noted between the two groups concerning local anesthetic volume, anesthetic supplementation, or akinesia. No complications were reported in either group. **Conclusions:** Medial canthal peribulbar blockade for cataract surgery using a short, fine (12mm, 28G) injection needle is comparable to that performed using the standard (25mm, 24G) needle in addition to being more simple, easy to perform, and less painful.

Keywords: Peribulbar – Medial canthus – Short needle – Cataract surgery

# Introduction

Patient comfort, safety, and low complication rates are the main requirements of any regional anesthetic block. Although akinesia is not essential for modern cataract surgery, some ophthalmic surgeons may prefer to operate on immobile eyes. Regional anesthesia is commonly performed for cataract surgery. A variety of local anesthesia techniques have been developed and refined [1]. Peribulbar block anesthesia (PBA) remains a popular choice for patients undergoing cataract surgery [2]. The use of a 25mm needle is the standard practice for extraconal injections [3]. Unnecessarily long needles may increase the risk of optic nerve injury, particularly in patients with shallow orbits [4]. The technique of medial canthus injection has advantages over other techniques including decreased pain during injection. Besides, injection in an avascular area decreases the risk of hemorrhage or intravascular injection [5]. Moreover, the preferred location of staphylomas is temporal, not nasal, and using a single injection to perform the block decreases the risk of global perforation [6].

This study aimed to compare the efficacy and safety of using a short, fine (12mm, 28G) needle to the standard (25mm, 24G) needle in performing peribulbar block

#### Correspondence to:

#### Dr. Rehab SK

 $^{*}$  Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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# Methods

# **Ethical considerations:**

This study follows the uniform requirements for manuscripts submitted to biomedical journals and has been conducted in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans.

We obtained approval from the Local Research Ethics Committee of the Research Institute of Ophthalmology on the 4th of July 2021, and written informed consents were obtained from all patients before participation in this study. We maintained data confidentiality by making code numbers for each patient.

We intended to share the individual de-identified participants' data. Data will be accessible through direct contact with the corresponding author, beginning 12 months and ending 36 months following article publication.

# Study design, settings and date:

This parallel-group (1:1), randomized, controlled study was conducted at the Research Institute of Ophthalmology, Egypt. The study started on July 10, 2021, and the patients' enrollment continued for 3 months.

# **Randomization and masking:**

We used the sealed, opaque, sequentially-numbered envelopes method for randomization and allocation concealment. We prepared 110 envelops. They were in the form of 2 sets of 55 identical, opaque, letter-sized envelopes. Each envelope contained a white allocation paper, marked as "Treatment A" (n=55) or "Treatment B" (n=55) and a sheet of single-sided carbon paper closest to the front of the envelope (with the carbon side facing the white paper). We sealed the envelopes and signed across the seal. We combined the two sets (110 envelopes) and shuffled them thoroughly. Then, we marked a number on the front of each envelope sequentially from 1 to 110 and placed them into a plastic container in numerical order ready for use.

An investigator (not involved in sequence generation and allocation concealment) assessed participants for eligibility and assigned eligible patients to receive peribulbar anesthesia using either short (12mm, 28G) or long (25mm, 24G) needle. The study participants and health professionals assessing the participants' outcomes were blinded to treatment allocation.

# **Eligibility criteria:**

We enrolled adult patients of both sexes, aged 18 to 85 years, for whom cataract surgery under local anesthesia was indicated, and had an American Society of Anesthesiologists (ASA) physical status I, II, or III.

We excluded patients who had a history of allergy to the study medications or severe coagulation disorders.

All patients were subjected to full history taking, physical examination, and routine investigations and were instructed to present to the operation room fasting (6 h for solids and 2 h for clear fluids). In addition, they were re-assessed again (brief history taking and vital signs) during waiting in the preoperative area just before performing the blockade.

# Intervention:

In the first intervention group (group A), participants received a single peribulbar injection at the medial canthus using a 12mm, 28G needle (International company for medical necessities, Egypt). Group B patients received a single peribulbar injection at the medial canthus using a 25mm, 24G needle (SAS CO For Syringe Manufacture, Egypt). After assessment of the vital data (heart rate, non-invasive blood pressure, and pulse oximetry) (Nihon Kohden - BSM-2301K; Nihon Kohden, Japan), a 22-G peripheral intravenous cannula was placed and premedication with 1 mg of midazolam (Midazolam 5 mg/ml; Sunny Pharmaceutical, Egypt) was performed in the preoperative holding area. Then 30-40 mg of propofol (Propofol-Lipuro 10 mg/ml; B Braun, Germany) were administered at the time of local anesthetic injection. The anesthetic mixture used was equal volumes of lidocaine HCl 2% (Debocaine 20 mg/ml; The Arab Company for Gelatin and Pharmaceutical Products, Egypt) and isobaric bupivacaine 0.5% (Sunnypivacaine 5 mg/ml; Sunny Pharmaceutical, Egypt) with 10 IU hyaluronidase per ml (Hyalase 1500 I.U.; Wockhardt, UK) (maximum volume was 10 ml). The injection site was between the caruncle and the medial canthus passing directly backward parallel to the medial orbital wall with the eye looking in the neutral gaze. After negative aspiration,

Correspondence to:

Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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the local anesthetic mixture was injected until achieving total drop and fullness of the upper eyelid (5-10 ml). Gentle digital compression was applied over the orbit for a total period of 3 minutes (20 seconds of compression followed by release for 10 seconds) to help spread of the local anesthetic mixture. Ocular akinesia was assessed after 3, 5, and 10 minutes using the simple akinesia score (0 = akinesia, 1 = partial akinesia, and 2 = normal movement) for the superior, inferior, medial, and lateral rectus muscle function giving a score of 8 for the 4 muscles. A score of 3 or less was considered a successful block. If the score was more than 3, supplementary anesthesia (2 ml) was injected at the involved quadrant using the same needle (size and gauge) used to perform the original block [7].

#### **Outcome measures:**

The primary outcome was the need for anesthetic supplementation. Safety was assessed looking for complications including systemic (e.g., respiratory and hemodynamic depression) and globe-related (globe perforation and retrobulbar hemorrhage) adverse events. Changes in vital data (blood pressure, oxygen saturation and pulse rate) were assessed every 5 minutes. Patients were followed-up for 24 hours after the operation.

#### Statistical analysis:

Statistical analysis was performed using Statistical Package for Social Sciences (IBM SPSS Statistics) for Windows, version 26 (IBM Corp., Armonk, N.Y., USA). Numerical variables were expressed as mean  $\pm$  standard deviation. The two groups were compared using unpaired student t-test. For categorical data, the variables were summarized as numbers and percentages. Pearson's Chi-square test for independence was used to examine the association between two categorical variables. Statistical significance was adopted at a *P*-value <0.05.

# Results

This study included 110 patients who were randomly allocated into 2 equal groups (allocation ratio is 1:1), with 55 patients in each group. Four patients (one from group A and three from group B) were excluded from the study after randomization as they were postponed for ophthalmological reasons (Figure 1).

Rehab SK et al. Comparison of two needle lenghts.

Table 1 shows no significant differences between the two groups regarding age, sex, or ASA physical status (all *P*-values >0.05).

Patients' Charact- eristics	Group A n=52	Group B n=54	P-value
Age (years) Range (Mean±SD)	30-81 (58.06±11.64)	18-80 (55.96±13.63)	0.396
Sex (female/male) n (%)	30/24 (55.6/44.4)	23/29 (44.2/55.8)	0.244
ASA physical status (I/II/III) n (%)	18/38/0 (33.3/66.7/0)	25/26/1 (48.1/50/1.9)	0.156

Table (1): Demographic features of the studied patients

Data are displayed as Mean ± SD or number (percentage).

ASA: American Society of Anesthesiologists; SD: standard deviation; n: number.

The mean globe axial length showed no significant difference between the two groups (*P*-value =0.225). We found a statistically significant difference between the two groups regarding the local anesthetic volume injected (*P*-value =0.024). We found no significant difference between the two groups regarding the need for anesthetic supplementation (*P*-value =0.200). There were no systemic or globe-related complications detected in both groups (Table 2).

#### Correspondence to:

Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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Characteristics	Group A	Group B	Р-
	n=54	n=52	value
Axial length (mm), Mean ± SD	24.39±2.39	24.96±2.41	0.225
Injected volume (ml), Mean ± SD	7.91±0.92	7.50±0.92	0.024*
Efficacy			
Did not need supplementation, n (%)	45 (83.3%) 9 (16.7%)	38 (73.1%) 14 (26.9%)	0.200
Needed supplementation, n (%)			
Systemic or globe- related complications, n (%)	0 (0%)	0 (0%)	1.00

**Table (2):** Comparison between axial length, injected volume, efficiency, and complications in the studied patients

Data are displayed as Mean ± SD or number (percentage). SD: standard deviation; n: number. \*Significant at a *P*-value <0.05.

#### Correspondence to:

Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: <u>rehabmsami@gmail.com</u>

Full list of author information is available at the end of the article.

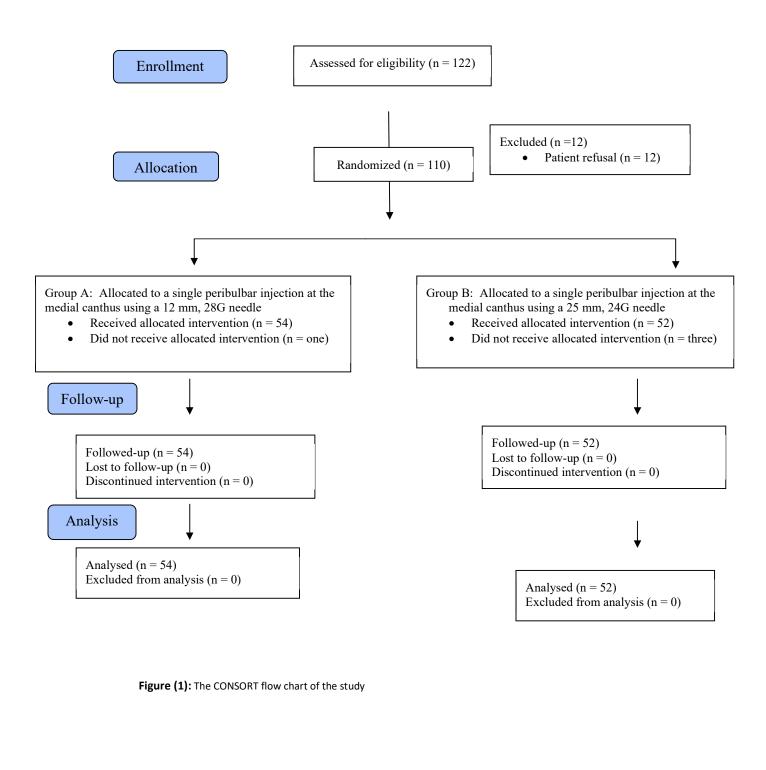
#### Discussion

While PBA is a popular anesthetic technique in patients undergoing ophthalmic surgery [8], the standard use of long needles with a length of approximately one inch may predispose to injury of the globe and optic nerve. The risk of injury by long needles increases particularly in patients with shallow orbits [4]. The use of needles with shorter lengths (12 to 15 mm) has been reported in the literature [9-18], with varying results of efficacy and safety compared with the standard PBA technique. The present study thus aimed to compare the efficacy and safety of using a 12mm needle to the standard 25mm needle in performing PBA at the medial canthus in cataract surgery. In this study, we found that the mean injected volume of local anesthetic was significantly higher in the 12mm group compared to the 25mm group (7.91±0.92 ml vs. 7.50±0.92 ml, respectively; P-value =0.024), though the difference may not be clinically significant. A plausible explanation is that the local anesthetic mixture was more anteriorly placed using a short needle and consequently a larger volume was required to enhance its spread towards the target nerves. Previous studies showed contradictory results as regards the injected volume of anesthetics. Mahfouz and Al Katheri [10] reported a significantly lower total volume of local anesthetics in the short needle group compared to that of the conventional needle group in patients undergoing cataract extraction  $(7.38 \pm 1.39 \text{ ml vs. } 9.64)$  $\pm$  1.81 ml; p=0.024). However, Riad and Ahmed [12] reported a comparable initial and total volume of injected anesthetics in PBA using 15mm and 25mm needles in cataract patients.

The efficacy of PBA was measured in the present study the percentage of required anesthetic bv supplementations. A slightly lower percentage of patients in the 12mm group required anesthetic supplementation, with no significant difference from the 25mm group (16.7% vs. 26.9%; P-value =0.200). The efficacy of PBA using short needles was demonstrated by Rizzo et al. [15] who examined the distribution of injected anesthetics using B-scan ultrasonography. The injection of a small volume of local anesthetic (5-6.5 ml) was demonstrated to surround the eye globe and produce higher need for anesthetic analgesia. The supplementation in PBA with long needles may be explained by the potential passing of the needle into the inferior orbital floor which causes a reduction of the spread of local anesthetic around the eye globe [9, 19].

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#### Correspondence to:

# Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: <u>rehabmsami@gmail.com</u>

Full list of author information is available at the end of the article.

©JORS http://jors.journals.ekb.eg/ The rate of requiring anesthetic supplementation while performing PBA with short needles varied widely among the studies. Mahfouz and Al Katheri [10] found that none of the short needle group patients required supplementation with local anesthetics compared to 18.8% of the standard 25mm needle group (p < 0.001). Riad [11] reported on 200 patients undergoing phacoemulsification under PBA using 12.5mm needle, with 9.5% of patients requiring supplemental injections. Ghali et al. [20] carried out a randomized clinical trial to assess the efficacy of single-injection PBA with a 16mm needle in patients with complicated cataracts, with only 7% in the PBA group requiring supplementation. Vasudevan and Mohanarangam [21] demonstrated the efficacy of a 13 millimeter long, 26 gauge needle in PBA for 350 patients undergoing a variety of ophthalmic surgeries, with 14% requiring supplemental injections. Meanwhile, Riad and Ahmed [12] stated that a slightly higher percentage of the 15mm needle group required supplemental injection compared to the 25mm needle group (21.6% vs. 18.7%; p>0.05). The differences in the percentage of supplemental injections required across the studies may be partially attributed to the variations in the initial injected volume of anesthetics. Other factors may be also implicated, such as differences in axial length of the globe, the surgeon's preferences for the required level of block, the type of the local anesthetic used, the site of needle introduction, and the nature of the ophthalmic intervention. The aforementioned studies, regardless of the variations in the reported rates, indicated that the use of a short needle for PBA was comparable or even superior to the use of a standard length needle in terms of block efficacy. Inconsistent with these findings, an audit by Van den Berg [17] reported a higher supplementation rate with the use of a 15mm needle compared with a 25mm needle (64 vs. 44%). However, this audit refers to an older time interval and surgical techniques as well as the experience of surgeons has improved since then. Moreover, digital compression at the time of injection is postulated to enhance efficacy by improving the spread of the anesthetic mixture deeper and more posteriorly to the equator of the eye globe. Another factor that explains the differences among the studies in terms of the efficacy of the short needle technique is the type of ophthalmic surgery. Results of PBA using a short needle in posterior segment surgery differs according to Riad et al. [13]. They reported both significantly higher total volume of local anesthesia (12.52 ml vs. 11.03 ml;

p=0.03) and supplementary injections (46.7% vs. 26.7%; p=0.01) in the short needle group, presumably due to the longer distance which the anesthetic had to pass till reaching its target. As regards complications of peribulbar anesthesia, none were encountered in either group in the present study. This could be attributed to both the site of needle introduction and its size. The medial canthus technique is considered safe owing to the lower number of important adjacent nerves, vessels, and muscles [5]. Moreover, staphyloma is more likely to be located temporally rather than nasally. The shorter length of the needle is logically anticipated to produce less local trauma [6]. Scott et al. [19] showed that a 16mm needle would reach up to the orbital equator and would not pass beyond it unless forcibly pushed. Besides, ElKhamary and Riad [9] assessed the anatomy of orbital structures at 12.5mm and 25mm depths in 50 subjects using three-dimensional magnetic resonance imaging. They concluded that there is a larger structurefree space at a depth of 12.5mm than at 25mm. Moreover, we used a single injection to perform PBA which may decrease the risk of global perforation compared to the double injection technique. The relevant literature suggests the higher safety of PBA with the use of short needles, reporting either the lack of complications or the occurrence only of limited, local, non-life-threatening complications. Rizzo et al. [15] assessed the safety and efficacy of PBA using a 16mm needle and a small volume of anesthetic in 857 patients undergoing various ophthalmic procedures. They reported that complications occurred only in 5 (6%) patients in the form of inferior lid hematoma (0.1%) and chemosis (0.5%). Riad and Ahmed [12] stated that no major life or sight-threatening complications were noted either with short or long needle use in their cohort of 150 patients. Riad [11] reported conjunctival chemosis in 15% of patients, but no life-threatening complications were encountered in their series of 200 patients. Ghali et al. [20] reported the occurrence of chemosis in 16% and subconjunctival hemorrhage in 2% in patients undergoing PBA in their study. Sherif et al. [16] conducted a prospective cohort study comparing the efficacy and safety of PBA using medial canthus single injection with a 13mm needle and posterior sub-tenon injection in patients with bilateral strabismus surgery. In the PBA group, no complications were reported. On the other hand, Mahfouz and Al Katheri [10] reported that the incidence of subconjunctival hemorrhage was

#### Correspondence to:

Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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significantly higher in the short needle group compared with the standard 25mm group (18 vs. 0.5%; P < 0.001).

#### Conclusion

The study revealed that peribulbar anesthesia via the medial canthal approach using the short, fine (12mm, 28G) injection needle was comparable to the technique using the standard (25mm, 24G) needle. It provided adequate akinesia requiring a single rather than multiple punctures, in addition of being more simple, easy to perform, and less painful.

#### Limitations

This was a single-center study. A multicenter-study on larger number of participants with different indications may be required.

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This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

#### **Conflicts of interest**

The authors declare that they have no conflicts of interest.

#### **Authors details**

Rehab S. Khattab <sup>1</sup>, Iman S. Aboul Fetouh <sup>1</sup>, Norhan A.

Sherif<sup>1</sup>, Noha A. Osama<sup>1</sup>, Mayada K. Mohamad<sup>1</sup>,

Nader N. Naguib<sup>2</sup>

- 1. Department of Anaesthesia; Research Institute of Ophthalmology, Giza, Egypt
- Department of Anaesthesia; Faculty of Medicine, Cairo University, Cairo, Egypt

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#### Correspondence to:

#### Dr. Rehab SK

\* Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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Correspondence to:

Dr. Rehab SK

 $^{st}$  Department of Anesthesia; Research Institute of Ophthalmology, Giza, Egypt

Email: rehabmsami@gmail.com

Full list of author information is available at the end of the article.

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