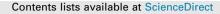
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### **Research article**

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#### ABSTRACT

*Background and Objectives:* Fentanyl or magnesium sulphate may improve the quality of peribulbar block. We compared the effects of adding either fentanyl or magnesium sulphate to peribulbar block in patients undergoing cataract surgery on the quality of globe akinesia.

*Methods:* 90 adult patients undergoing cataract surgery were randomly allocated into three groups. Peribulbar block was performed by a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, hyaluronidase 150 IU diluted in normal saline to a total volume of 10 ml in control group. 20 µg fentanyl and 50 mg magnesium sulphate (10%) were added to the same mixture in fentanyl and magnesium groups respectively. Onset and duration of lid and globe akinesia, adequate time to start surgery and duration of post-operative analgesia were recorded.

*Results:* Addition of fentanyl significantly enhanced the onset of lid  $(1.54 \pm 0.43 \text{ min})$  and globe akinesia  $(2.19 \pm 0.75 \text{ min})$  as well as adequate time to start surgery  $(6.23 \pm 1.8 \text{ min})$  compared to both control (P < 0.05) and magnesium sulphate (P < 0.05) groups while the comparison between control and magnesium sulphate groups was statistically insignificant (P > 0.05). Time of first analgesic request was significantly prolonged in both fentanyl and magnesium sulphate groups compared to the control group (P < 0.05).

*Conclusions:* Addition of fentanyl (2 µg/ml) or magnesium sulphate (50 mg) to peribulbar block in patients undergoing cataract surgery equally prolongs the duration of postoperative analgesia. In addition to this effect, fentanyl fastens the onset lid and globe akinesia and provides better akinesia score. © 2016 Publishing services by Elsevier B.V. on behalf of Egyptian Society of Anesthesiologists. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

#### 1. Introduction

Regional anesthesia is the technique of choice for cataract surgery. Because of its safety, ease to perform and efficacy, peribulbar anesthesia is the most common regional technique used for Cataract surgery [1].

Several adjuvants can be used with local anesthetic solutions to improve the quality of peribulbar block as hyaluronidase [2], clonidine [3], and neuromuscular blockers [4].

Fentanyl is a synthetic narcotic frequently added to local anesthetics, prolonging its action to provide better analgesia and anesthesia [3].

Magnesium is a physiological blocker of calcium channel and a noncompetitive N-methyl-D-aspartate (NMDA) receptor antago-

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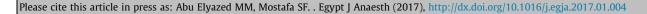
nist [5]. It has been used as an adjuvant to local anesthetic solutions in different regional anesthesia techniques to improve the quality and duration of anesthesia [6].

The aim of this study was to compare the effects of adding either fentanyl or magnesium sulphate to peribulbar anesthesia in patients undergoing cataract surgery on the quality of globe akinesia.

#### 2. Patients and methods

After obtaining approval from the Hospital Ethics Committee (Faculty of medicine, Tanta University, 30913/05/16), registration in the Pan African Clinical Trials Registry (PACTR201606001669349, on 6/2016) and informed written consent from the patients, a prospective, randomized, double-blind trial on adult patients aged 40–70 years, of either gender, ASA I-II, undergoing cataract surgery was carried out. The duration of the study was 6 months. All patients' data was confidential with secret codes and in a private file for each patient. All given data

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was used for the current medical research only. The study protocol was explained to each patient during the preoperative visit. Any unexpected risks encountered during the course of the research were cleared to the participants as well as the ethical committee. All patients and investigators were blinded about the local anesthetic solution used throughout the whole duration of the study.

#### 2.1. Exclusion criteria

Patient refusal, coagulopathy or history of anticoagulant therapy, allergy to local anesthetics, axial length >28 mm, posterior staphyloma, disturbed conscious level, active respiratory disease, poor communication ability as deafness, patients with excessive tremors or agitations, impaired orbital/periorbital sensations, and patients with glaucoma.

No sedative premedication was administered in the preoperative period. In the operating room, an intravenous line was inserted and standard monitors (electrocardiography, oxygen saturation, and noninvasive blood pressure) were applied to all patients.

Patients were randomly allocated into three groups. Randomization was done using computer-generated numbers in sealed opaque envelopes and each patient selected the envelope which determined his group.

**Group I (Control group):** patients received a peribulbar block using a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, hya-luronidase 150 IU diluted in normal saline to a total volume of 10 ml.

**Group II (Fentanyl group):** patients received a peribulbar block using a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, hyaluronidase 150 IU and fentanyl 20  $\mu$ g diluted in normal saline to a total volume of 10 ml.

**Group III (Magnesium sulphate group):** patients received a peribulbar block using a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, hyaluronidase 150 IU and magnesium sulphate 10% (50 mg) diluted in normal saline to a total volume of 10 ml.

The studied local anesthetic solution for peribulbar block was prepared by an anesthesiologist resident who had no subsequent role in the study.

Each patient received peribulbar block via a single percutaneous inferolateral approach using a 25 gauge, 25 mm needle [7]. With the eye fixed in the primary gaze position, the injection was performed at the junction between the lateral one third and medial two thirds of the inferior orbital rim with the needle directed slightly medially and cephalad. After negative aspiration, 7–10 ml of the local anesthetic mixture was injected over 30–40 s. Injected volume of local anesthetic varied according to the degree of filling of the orbit and the rate of onset of ptosis during injection.

A Honan balloon set at 30 mmHg was then applied to produce intermittent compression for 10 min in all groups.

Primary outcome was the onset of globe akinesia. Onset of akinesia was assessed by evaluation of the movements of eyelid (lid akinesia) and the 4 rectus muscles (globe akinesia). Evaluation of lid akinesia (lid closure and squeezing by orbicularis and lid opening by the levator palpebrae muscle) as well as globe akinesia were assessed before peribulbar block, 1 min, 3 min, 5 min, 8 min and 10 min after performing the block. The degree of lid and globe akinesia was evaluated using a 3-point scoring system: [8] 0 = complete akinesia, 1 = partial akinesia, and 2 = no akinesia.

Lid akinesia was assessed by asking the patient to widely open both eyelids followed by squeezing them maximally. Globe akinesia was assessed by scoring the ocular movements in each of the four directions of gaze (upward, downward, nasal and temporal) with a total score of the four directions ranging from (0 to 8).

Onset of sensory block was assessed by loss of the corneal reflex. The time for adequate condition to start surgery was recorded and defined as corneal anesthesia together with an eyelid akinesia score of 0 and an ocular akinesia score  $\leq 1$  in each direction of gaze [9]. If the adequate condition to begin surgery was not observed 10 min after block, supplementary anesthesia (3 mL) was injected into the involved quadrant using the same length needle as for the primary block. Any patient who required supplemental injection was excluded from the study.

The duration of akinesia was assessed by the recovery of ocular and eyelid movements. Postoperative pain was assessed at the end of surgery, 30 min, 1 h, 2 h, 4 h, 6 h and 8 h postoperative. Assessment was done using a verbal rating scale (VRS) ranging from 0 (no pain) to 10 (unbearable pain). Paracetamol tablet 500 mg was given if a VRS was  $\geq$  5. The time to 1st analgesic request (time interval between injection of local anesthetic solution to the 1st requirement of postoperative analgesia) was recorded. Any side effects or complications of the block (hemorrhage, globe perforation, brain stem anesthesia, drowsiness, nausea, vomiting, and dizziness) were recorded, and appropriate management was done. The incidence of hypotension, bradycardia (defined as 20% decrease of mean arterial pressure and heart rate from pre- block value) and hypoxia (O2 saturation <90% on room air) were also recorded. All measures were assessed by an investigator who was blinded to the local anesthetic solution used.

#### 2.2. Statistical analysis

Calculation of the sample size was based on the onset of globe akinesia. Depending on the results of previous study [3], a sample size of at least 27 patients was found to be needed to detect a difference at the 5% significance level and give the trial 90% power. We used SPSS 16 for statistical analysis. Quantitative data was described as mean  $\pm$  SD and were analyzed using One-way ANOVA with post-hoc Turkey's HSD Test. Categorical data were described as number or frequencies (%) and Chi-square test was used for comparison among groups. P-value < 0.05 was considered significant Fig. 1.

#### 3. Results

30 patients were enrolled in each group. Patients' characteristics showed no statistical significant differences as regards age, sex, weight and ASA physical status. Type and duration of surgery, globe axial length as well as the injected volume of local anesthetic solutions were all comparable among the three studied groups Table 1.

Addition of fentanyl significantly enhanced the onset of corneal anesthesia, the onset of both lid and globe akinesia as well as adequate time to start surgery compared to both control and magnesium sulphate groups while addition of magnesium sulphate showed no statistical significance compared to the control group in either parameters Table 2.

Pre-operative globe akinesia score was comparable among the three groups. At 1 min, 3 min, 5 min and 8 min after the block, globe akinesia score was significantly lower in fentanyl group as compared to control (P < 0.05) and magnesium sulphate groups (P < 0.05) while there was no statistical difference between control and magnesium sulphate groups (P > 0.05). At 10 min after peribulbar block, globe akinesia score was insignificantly different among the three groups (P > 0.05) Fig. 2.

At 1 min, 3 min and 5 min after peribulbar block, lid akinesia score was significantly lower in fentanyl group as compared to control (P < 0.05) and magnesium sulphate groups (P < 0.05). At these times, lid akinesia score in control group was statistically insignificant as compared to magnesium sulphate group (P > 0.05). At 8 min and 10 min after peribulbar block, lid akinesia score was comparable among the three groups (P > 0.05) Fig. 3.

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