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Research article

Fentanyl versus magnesium sulphate as adjuvant to peribulbar anesthesia in cataract surgery☆

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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 postoperative analgesia were recorded.
Results: Addition of fentanyl significantly enhanced the onset of lid (1.54 ± 0.43 min) and globe akinesia (2.19 ± 0.75 min) as well as adequate time to start surgery (6.23 ± 1.8 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.

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 antagonist [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%, hyaluronidase 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 μg 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 $\leqslant 1$ 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 $\geqslant 5$. 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 ± 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.

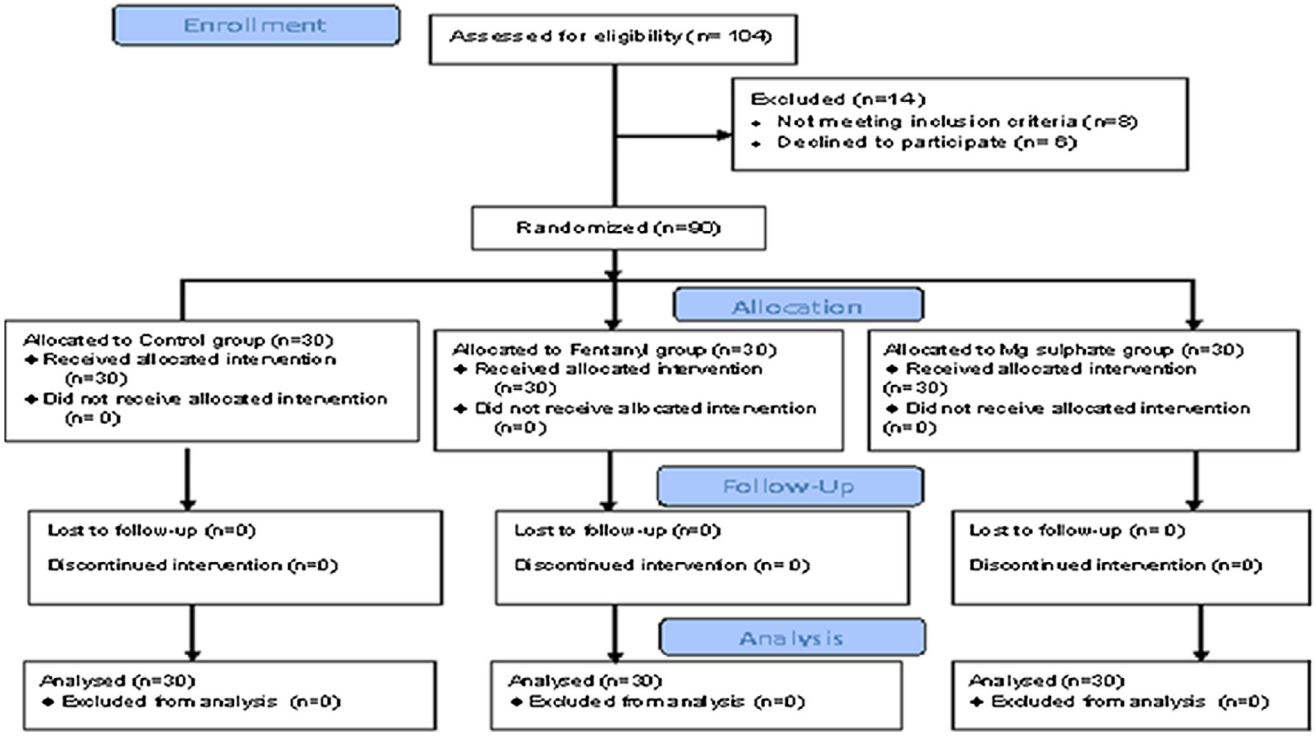

Fig. 1. CONSORT Flow Diagram of participants through each stage of a randomized trial.

Table 1
Perioperative patient's characteristics presented as mean ± SD or number (%).

		Control group	Fentanyl group	Magnesium sulphate group	P value
Age (year)		54.83 ± 7.28	55.80 ± 7.82	56.33 ± 8.32	0.754
Gender M/F		18/12	17/13	20/10	0.721
Weight (kg)		77.73 ± 8.59	79.90 ± 7.75	78.53 ± 7.88	0.578
Type of cataract surgery	Open	7 (23.3%)	6 (20%)	4 (13.3%)	0.602
	Phaco	23 (76.6%)	24 (80%)	26 (86.7)	
Axial length (mm)		25.58 ± 1.35	25.46 ± 1.37	25.26 ± 2.36	0.776
Surgical duration (min)		34.90 ± 11.33	34.17 ± 10.64	33.27 ± 8.73	0.828
Injected volume (ml)		7.70 ± 0.79	7.2 ± 0.79	7.55 ± 0.72	0.117
Complications	Sedation	0	1 (3.3%)	0	0.364
	Dizziness	0	0	1 (3.3%)	0.364
	Pain on injection	2 (6.7%)	1 (3.3%)	1 (3.3%)	0.769

Table 2
Criteria of peribulbar block in the three groups presented as mean ± SD.

	Control group	Fentanyl group	Magnesium sulphate group	p	P1 (%95 CI)	P2 (%95 CI)	P3 (%95 CI)
Anesthesia onset (min)	2.31 ± 0.43	1.23 ± 0.43	2.27 ± 0.63	<0.001*	<0.001* (0.864; 1.310)	0.767 (0.864; 1.310)	<0.001* (0.766; 1.324)
Lid akinesia onset (min)	2.82 ± 0.62	1.54 ± 0.43	2.74 ± 0.77	<0.001*	<0.001* (1.007; 1.557)	0.832 (−0.280; 0.443)	<0.001* (0.875; 1.525)
Globe akinesia onset (min)	3.77 ± 0.96	2.19 ± 0.75	3.64 ± 0.98	<0.001*	<0.001* (1.131; 2.023)	0.611 (−0.374; 0.630)	<0.001* (0.994; 1.902)
Adequate time to start surgery (min)	8.43 ± 1.10	6.23 ± 1.8	8.30 ± 1.44	<0.001*	<0.001* (1.420; 2.980)	0.689 (−0.531; 0.798)	<0.001* (1.219; 2.914)
Lid akinesia duration (min)	109.50 ± 16.83	175.83 ± 38.19	171.67 ± 24.19	<0.001*	<0.001* (50.92; 81.75)	<0.001* (51.37; 72.97)	0.616 (−12.42; 20.75)
Globe akinesia duration (min)	135.83 ± 24.53	215.50 ± 39.99	208.17 ± 27.71	<0.001*	<0.001*(62.45;96.89)	<0.001*(58.80; 85.87)	0.413(−10.50; 25.17)
Time to 1st analgesia (min)	165.17 ± 27.24	258.83 ± 41.31	249.33 ± 26.05	<0.001*	<0.001*(75.52; 111.81)	<0.001*(97.95; 70.38)	0.292(−8.43; 27.43)

CI (confidence interval).
P represents comparison among the three groups. P1 represents comparison between control group and fentanyl group. P2 represents comparison between control group and magnesium sulphate group. P3 represents comparison between fentanyl group and magnesium sulphate group.
* Indicate P < 0.05.

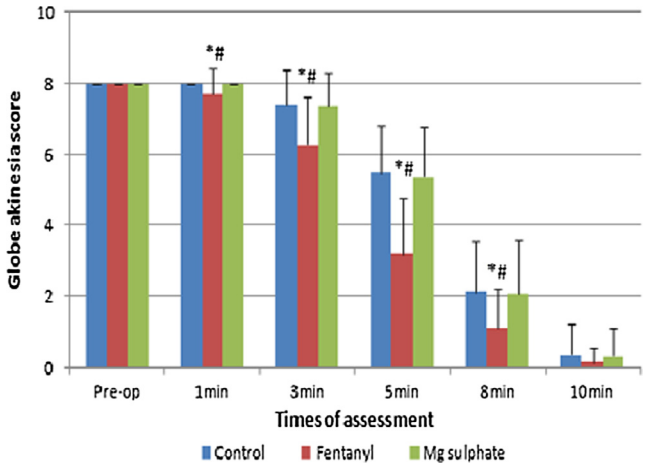

Fig. 2. Globe akinesia score changes in the three groups. * indicates statistically significant difference between control group and fentanyl group. # indicates statistically significant difference between fentanyl group and magnesium sulphate group. Pre-op; preoperative.

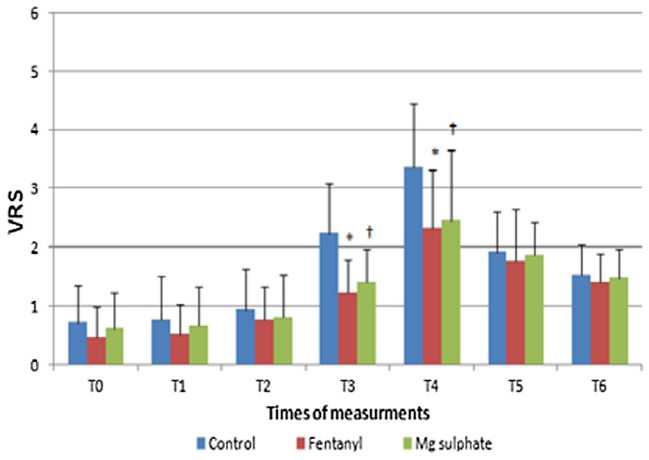

Fig. 4. Verbal rating scale changes in three groups. * indicates statistically significant difference between control group and fentanyl group. † indicates statistically significant difference between control group and magnesium sulphate group. VRS: Verbal rating scale.

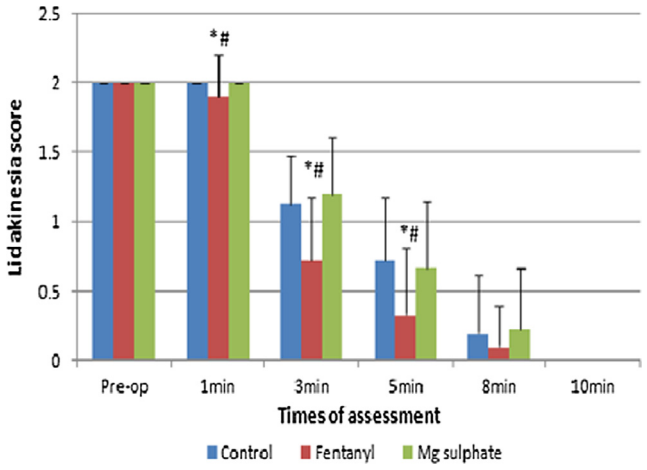

Fig. 3. Lid akinesia score changes in the three groups. * indicates statistically significant difference between control group and fentanyl group.# indicates statistically significant difference between fentanyl group and magnesium sulphate group. pre-op; preoperative.

Both fentanyl and magnesium sulphate significantly prolonged the duration of lid and globe akinesia compared to the control group ($P < 0.05$) while the difference between them was statistically insignificant ($P > 0.05$) Table 2.

Time of first rescue analgesic request was significantly prolonged in both fentanyl and magnesium sulphate groups as compared to control group Table 2.

Values of VRS in studied groups are shown in Fig. 4.

No major complications were encountered in any of the studied groups Table 1.

4. Discussion

The results of our research showed that the addition of fentanyl 2 μg/ml to the anesthetic solution for peribulbar block for cataract surgery significantly improved the quality of the peribulbar block., fastened the onset of anesthesia as well as the onset of both lid and globe akinesia with better akinesia score than control and magnesium sulphate groups. So the optimal time to start surgery was lesser than the other two groups. The addition of fentanyl or magnesium sulphate to local anesthetic solution for peribulbar block equally prolonged duration of lid and globe akinesia as well as duration of postoperative analgesia compared to the control group.

Besides its central mediated analgesia through stimulation of central opioid receptors [10], fentanyl acts directly on the peripheral opioid receptors and thus enhances the quality of regional anesthesia when added to local anesthetics [11]. Opioid receptors are expressed in the dorsal root ganglion (DRG) neurons [12] and transported centrally and peripherally to the nerve terminals. Opioid may exert a peripheral "analgesic" effect by binding to opiate receptors on primary afferent fibers in peripheral sites [13]. On activation, the opioid receptors bind to inhibitory G-proteins and inhibit the production of cyclic AMP and/or directly interact with K^+, Ca^{2+}, and other ion channels in the membrane. So, the analgesic effects of opioids result from the decreased nociceptor excitability, the reduced propagation of action potential, and decreased release of excitatory pro-inflammatory neuropeptides (substance P and calcitonin gene related peptide) at central and peripheral nerve terminals [14]. Also, fentanyl is proved to have a local anesthetic action [15].

Our results are on line with the results of Abo El Enin et al. [16] who studied the effects of adding fentanyl to local anesthesia solution (5 ml mepivacaine 3% + 1 ml hyaluronidase (150 mcg) + 3 ml bupivacaine 0.5%) for peribular block in 40 patients undergoing vitrectomy due to vitreous hemorrhage not associated with retinal detachment. They found that the addition of fentanyl to local anesthetic solution accelerates the onset and prolongs the duration of lid and globe akinesia and decreases the postoperative analgesic consumption in comparison to control group. Youssef et al. [3] compared the effect of using fentanyl versus clonidine adjuvants to local anesthetic solution for peribulbar block in 90 patients scheduled for cataract surgery. They stated that the addition of either clonidine or fentanyl to the local anesthetic mixture accelerates the onset and prolongs the duration of the peribulbar block with a longer period of postoperative analgesia as compared to the control group. The addition of clonidine provided longer duration of peribulbar block as compared to fentanyl. On the other hand, Kamel et al. [17] concluded that a concentration of ⩾2–3 μg/ml of fentanyl didn't affect neither the onset nor the duration of both lid and globe akinesia when added to local anesthetics for peribulbar block in patients undergoing cataract surgery. They stated that this concentration only improved the quality of postoper-

ative analgesia. Improved analgesia following the addition of fentanyl to local anesthetic solution in various nerve blocks had been documented in previous studies [18,19]. Conversely, other studies have been unable to detect improved analgesia following co-administration of local anesthetic and fentanyl [20].

The results of our study showed that the addition of magnesium sulphate at dose of 50 mg to the local anesthetic solution for peribulbar block did not affect neither the onset of anesthesia nor lid or globe akinesia but it prolonged the duration of lid and globe akinesia and duration of postoperative analgesia. Analgesic effects of magnesium sulphate on peripheral nerves may be due to the antagonism of NMDA receptors thus preventing central sensitization from peripheral nociceptive stimulation [21]. Also, magnesium competitively blocks calcium influx into presynaptic endings leading to reduced acetylcholine release [22]. The surface charge theory is another possible mechanism [21]. Peripheral nerve blockade due to local anesthetics may be enhanced by modulation of the external magnesium concentration bathing a nerve bundle. Moreover, the high concentration of Mg^{2+} attracted by the negative charges of the outer membrane surface affected Na^{+} channel gating and could cause hyperpolarization and inhibition of nerve conduction [23].

Improved analgesia following the addition of magnesium sulphate to local anesthetic solution in various nerve blocks had been documented in previous studies [5,21].

Hamawy et al. [9] compared the effects of using rocuronium versus magnesium sulphate as an adjuvant to local anesthetic solution for peribulbar block in 75 patients scheduled for cataract surgery. They concluded that the addition of magnesium sulphate (50 mg) did not affect neither the onset of the block nor the akinesia score. But they did not assess the postoperative pain and postoperative analgesic consumption in their study. On the other hand, Sinha et al. [24] studied the effects of adding magnesium sulphate (50 mg) to local anesthetic solution (4.5 ml of 2% lidocaine, 4.5 ml of 0.5% bupivacaine with150 IU hyaluronidase) for peribulbar block in 60 patients. In contrary to our work, they stated that the addition of magnesium sulphate at dose of 50 mg to the lidocaine-bupivacaine mixture for peribulbar block accelerates the onset of akinesia without any adverse effects. Some studies have been unable to detect improved analgesia following co-administration of Local anesthetics and magnesium sulphate for peripheral nerve block [25].

The first limitation in our work was the limited number of patients investigated in the study. Another limitation is that we didn't assess sedation score in details. We only recorded occurrence of sedation as one of the possible complications.

5. Conclusion

The addition of fentanyl (2 μg/ml) or magnesium sulphate (50 mg) to local anesthetic solution for peribulbar block in patients undergoing cataract surgery equally prolongs the duration of postoperative analgesia. In addition to this effect, fentanyl fastens lid and globe akinesia and provides better akinesia score.

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Meetings where the work has been presented

None.

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