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ORIGINAL RESEARCH ANESTHESIA FOR EYE / ENT SURGERY

Comparative study between rocuronium and magnesium sulfate as adjuvants to local anesthetics for peribulbar block

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ABSTRACT

Background & Objective: Peribulbar anesthesia is frequently used in cataract surgeries. Compared to retrobulbar anesthesia, this approach is associated with less significant consequences. However, the prolonged onset of orbital akinesia and the frequent need for block replenishment are considered drawbacks. We aimed to investigate the impact of adding rocuronium and magnesium sulfate to a commonly used local anesthetic combination on the onset of corneal anesthesia and the degree of lid and globe akinesia during peribulbar block in ocular surgeries.

Patients and Methods: This prospective double-blinded randomized study was conducted in the ophthalmic surgery operating theater, Ain Shams University Hospital from January 2019 to April 2020. We enrolled 75 patients from both sexes, with American Society of Anesthesiology (ASA) physical status I–III, ages 40-80 y, and an axial globe length less than or equal to 26 mm planned for cataract surgery under peribulbar block in the study following institutional ethical board approval and written informed patient consents. Patients were randomly divided into three groups, 25 patients per group, based on the drugs they received: Group O (control group): received local anesthetic + 0.9% normal saline (1 ml). Group M: received local anesthetic + magnesium sulphate 50 mg in normal saline. Group R: received local anesthetic + rocuronium at a dose of 0.06 mg/kg (maximum 5 mg) in normal saline.

Results: Our study found statistically significant more rapid onset of action (mean time to start surgery) in rocuronium group (7.00 \pm 1.22 min) than control group and magnesium sulfate group (9.00 \pm 1.47 and 9.00 \pm 1.15 min) respectively, (P < 0.001); Moreover, no significant difference was noted between control group and magnesium sulfate group. In addition, no relevant difference was reported regarding duration of surgery between the groups.

Conclusion: During cataract surgery, the addition of rocuronium to the local anesthetic mixture in the peribulbar nerve block has been found to enhance ocular akinesia and corneal anesthesia. Furthermore, the use of rocuronium demonstrated a significantly faster onset and shorter time needed to achieve the appropriate conditions to initiate the surgical procedure compared to the use of magnesium sulfate. Addition of magnesium sulfate showed good results regarding akinesia, corneal anesthesia and need for supplementary injections but it did not significantly faster the onset of block and hence the time to start surgery.

Key words: Cataract; Magnesium Sulfate; Peribulbar Block; Rocuronium

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1. INTRODUCTION

For cataract surgery, peribulbar anesthesia is frequently employed. Compared to retro-bulbar anesthesia, this method has less major side effects. The sluggish start of orbital akinesia and recurrent requirement of block replenishment are drawbacks, though. Adjuvant medications including sodium bicarbonate, adrenaline, and hyaluronidase have all been used as additives to the local anesthetic combination used for peribulbar anesthesia in an effort to overcome these limitations, but their results have been inconsistent. Vecuronium and atracurium, two muscle relaxants, have also been used as additives to the local anesthetic combination and have been demonstrated to enhance peribulbar anesthesia. However, atracurium has the potential to cause local hyperemia, which is undesirable. This is secondary to its histamine-releasing properties. The effects of rocuronium, which lacks this side effect and has a quicker beginning of action, on the quality of peribulbar nerve block, in terms of start time and the requirement for additional injection of local anesthetics, have not yet been thoroughly explored.¹

For many years, pre-eclampsia patients have utilized magnesium sulphate empirically to control their fits. Magnesium ions are necessary for many metabolic processes, and a deficit could have clinically significant negative impacts. Its pharmacological characteristics have just lately been fully understood in several cases. About 300 enzyme systems are activated by magnesium, which is the body's fourth most common cation. Many of these enzyme systems are involved in energy metabolism. Owing to the interesting scientific underpinnings of its potential anti-nociceptive action. The primary mechanisms underlying these effects include physiological calcium antagonistic voltage regulated calcium inflow into the cells and noncompetitive antagonistic regulation of N-Methyl D-Aspartate (NMDA) receptors.²

This study's goal was to determine how adding rocuronium and magnesium sulphate to a traditional local anesthetic combination affects the onset of corneal anesthesia, as well as globe and lid akinesia after peribulbar block in ocular operations.

2. METHODOLOGY

This prospective double-blinded randomized study was done in the ophthalmic surgery theater of the Ain Shams

university hospital from January 2019 to April 2020. 75 cases from both sexes, with ASA physical status I–III, ages 40–80, and an axial globe length of less than or equal to 26 mm and planned to do cataract operation under peribulbar nerve block were included in the study after institutional ethical board authorization and signed informed patient consent.

Refusal of the procedure or take part in the study. Patients with any known systemic restrictions (as severe hypertension). Patients with local anesthetic allergies. (axial length > 26 mm) High myopes. Single eye. Those who have complicated vitreous haemorrhage. individuals with eye infections. patients with diminished orbital sensation. patients who have retinal detachment. Expected lengthy surgery (more than 2 hours). More than 1.4 INR. less than 100,000 platelets. patients with mental disability or reduced consciousness.

Based on the findings of an earlier research, the sample size was determined with an alpha value of 0.05 and an 80% research power. We included 25 cases in each category to account for potential dropout cases.⁵

The advantages and hazards of peribulbar nerve block, as well as the drugs administered before participating in the study, were discussed with each case. Prior to participating in the trial, all patients signed their consents.

Study interventions

Patients were divided into three groups at random based on the drugs they received (25 patients per group): Group O (control group): received local anesthetic mixture + 0.9% normal saline (1 ml). Group M: received local anesthetic mixture + magnesium sulphate 50 mg in 1 ml of 0.9% normal saline. Group R: received local anesthetic mixture + rocuronium at a dose of 0.06 mg/kg (maximum 5 mg) in 1 ml normal saline.

Preoperative evaluation: At patients' preoperative visits, full history was taken, physical examination was done. When appropriate, preoperative examinations such as evaluations of the coagulation profile, metabolic profile, complete blood picture, and ECG were carried out. Patients were also given a detailed explanation of the research protocol and the anesthetic procedure.

Monitoring: Upon arrival each patient to the operating theater, standard monitors were connected to the patient

including Pulse oximeter, five lead ECG, and non-invasive blood pressure monitoring.

Anesthetic technique: Before receiving anesthesia, fasting for at least six hours was required. Under strict aseptic conditions, the surgery was carried out in the operating theater. An intra-venous cannula was used to secure an intravenous access. Nasal prongs were used to provide oxygen (2 L/min).

Pre-medications of 1 mg of midazolam and 25 mcg of fentanyl were given to all patients 3 minutes preprocedural. Additionally, 0.4% benoxinate hydrochloride eye drops were used to provide topical anesthesia for the conjunctiva and cornea 3 minutes preprocedural.

A senior anesthetist who was not aware of the components of the mixture injected will perform the peribulbar block while the patients are lying supine in the operating room. All patients will receive a standard peribulbar anesthetic block utilizing 9 ml of a local anesthetic mixture consisting of 4.5 ml of 2% lidocaine hydrochloride and 4.5 ml of 0.5% bupivacaine combined with hyaluronidase enzyme (150 U) to hasten tissue penetration.

The patients will then receive the following combinations according to their group: Group O (control group): local anesthetic mixture + normal saline (1 ml). Group M: local anesthetic mixture + 50 mg magnesium sulfate in normal saline.³ Group R: local anesthetic mixture + rocuronium at a dose of 0.06 mg/kg (maximum 5 mg) in normal saline.⁴

After sterilization, 5 ml of the solution will be injected into the medial canthus peribulbar area and the infrotemporal area, with a sufficient amount of time and a light orbital massage lasting at least 40 seconds between each injection. The 25G short bevel needle will be used to provide the injection (25 mm in length). The eye will then be gently compressed for one minute to soften it before surgery and to let the local anesthetic mixture diffuse.

Data collection: At 2.5, 5, 7.5, and 10 min after injection, corneal anesthesia was tested by a small piece of cotton wool, and the mobility of the eyelid and globe was scored to estimate the effectiveness of the block (assessment was carried out by another anesthesiologist who did not know the nature of the injected solution in each patient). The following was included in the motor block evaluation:

Lid akinesia was assessed using a three-point rating scale (0-2), where "0" denoted full lid akinesia, "1" denoted either or both lid margins' partial movement, and "2" denoted either or both lid margins' normal movement

(closing and squeezing the eyelid by the orbicularis and opening of the eyelid by the levator palpebrae muscle).

Patients participating in the study were instructed to fully open their eyelids and then forcefully close them as tightly as possible to test for lid akinesia.

Globe akinesia was assessed by a three-point rating scale (0-2) for each one of the four main directions (nasal, temporal, upward, and downward). If eye movement was normal, it received a score of "2" in each direction, '1' if it was limited, And "0" in the absence of any directional movement (a total of 8 points). The result of adding the lid akinesia score (0-2) and the globe akinesia score (0-8) was a total of 10.

Hemodynamic data: Throughout the whole procedure, pulse, mean arterial blood pressure, and oxygen saturation (SpO_2) were documented every 15 min. During the first two hours following the surgery, they were recorded every 30 min. Blood pressure and heart rate that were 20% lower than pre-block values were considered hypotension and bradycardia, respectively.

Time to achieve adequate condition to proceed with surgery: A timer was used to record the time needed until the patient was in a sufficient condition to start surgery, which was determined to be the achievement of corneal anesthesia along with a score of 1 in each direction for ocular movement and a 0 score for lid akinesia. According to the anesthesiologists' evaluation, a supplement dose of 2% lidocaine hydrochloride (3 ml) was given infro-temporally or medially if the patient's state was not sufficient to start surgery after 10 min of conducting the block.

The visual analogue scale (VAS), which includes two anchor points: "0" for no pain and "10" for the most agonizing worst possible pain, was used to evaluate intraoperative pain for all patients. All negative events were documented.

Statistical analysis

Recorded data were analyzed using the statistical package for social sciences, version 20.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were expressed using the mean and standard deviation (SD). The qualitative data were expressed using frequency and percentage. The following tests were done: When comparing between more than two means, a one-way analysis of variance (ANOVA) was used. Post Hoc test: Tukey's test was used for multiple comparisons between several variables. Kruskal Wallis test was employed for multiple-group comparisons in non-parametric data & Mann Whitney U test was employed for two-group comparisons in non-parametric data. Chi-square (x^2) test of significance was utilized to compare proportions between qualitative parameters.

3. RESULTS

The demographic features, including age, sex, ASA physical status and were equivalent and there was no statistical differences (P > 0.05) between the groups (Table 1). can be seen based on demographic information There was no differences in the eye globe axial length (P > 0.05) in the three groups (Table 1).

There was significantly higher mean time to start surgery in Group O and Group M compared to Group R with P < 0.001; while duration of surgery was statistically equivalent between the three groups with P > 0.05 (Table 2). Using Tukey's test, the small alphabets show the value is significantly different at P < 0.05.

There was no significant difference between groups as regards pulse rates, MAP or SpO_2 in the overall time, with P > 0.05.

There was no significant difference between groups as regards pain during surgery (P = 0.223). Need for supplemental injection was significantly more (P = 0.040) in Group O and Group M as compared to Group R (Table 3).

Table 4 shows that there was a decrease in all of the three groups over the time, but there was significant decrease in Group O, followed by Group M and then Group R. But there was no significant difference between Group Difference between both Groups and Group R at 2.5 min. At 5 min and 7.5 min, there was significant difference between the 3 groups with P = 0.024 for Group O vs. Group M, P < 0.001 for Group O vs. Group R and P =0.035 for Group M vs. Group R at 5 min and 7.5 min. At 10 min there was no significant difference between Group O and Group M (P = 0.639) and significant difference between the both groups and Group R (P <0.001).

Values in each row which have different letters are significantly different at (P < 0.05)

There was significantly higher pain of corneal anesthesia in Group O, compared to Group M and Group R, with P = 0.003 at 2.5 min; while during the rest of the period the difference between groups was insignificant, with P > 0.05 (Table 5).

4. DISCUSSION

Our study proved that addition of rocuronium to the local anesthetic solution for peribulbar block during cataract surgery promotes corneal anesthesia and ocular akinesia and decreases the need for additional injections without side effects and that was superior to magnesium sulfate in terms of rapid onset and time needed to achieve adequate conditions to begin surgery. However, magnesium sulfate gives good results regarding akinesia,

Table 1: Comparison betwe	en groups based	on demographic	information.		
Demographic data	Group O (n = 25)	Group M (n = 25)	Group R (n = 25)	Test value	P-value
Age (y)	56.36 ± 5.50	56.92 ± 4.75	56.32 ± 5.54	<i>F:</i> 0.101	0.904
Sex					
Female	14 (56.0%)	13 (52.0%)	15 (60.0%)	<i>x</i> ² :0.325	0.850
Male	11 (44.0%)	12 (48.0%)	10 (40.0%)		
ASA classification					
I	7 (28.0%)	6 (24.0%)	8 (32.0%)	<i>x</i> ² :0.635	0.959
Ш	13 (52.0%)	15 (60.0%)	13 (52.0%)		
III	5 (20.0%)	4 (16.0%)	4 (16.0%)		
Globe axial length (mm)	23.00 ± 1.22	22.76 ± 1.20	23.00 ± 1.35	F:0.302	0.741
Data presented as mean ± SD or	n (%); P < 0.05 was	considered as signifi	icant		

Table 2: Comparison between groups regarding surgery details.					
Data of surgery	Group O (n = 25)	Group M (n = 25)	Group R (n = 25)	F-test value	P-value
Time to start surgery (min)	9.00 ± 1.47^{A}	9.00 ± 1.15^{A}	7.00 ± 1.22 ^B	20.000	< 0.001
Duration of surgery (min)	27.92 ± 2.72	25.20 ± 3.19	26.92 ± 2.22	2.113	0.103
Data presented as mean ± SD o	r n (%); The small al	phabets show the val	ue is significantly diff	erent at P < 0.0	05

Table 3: Comparison between groups regarding intra-operative pain.					
Group O (n = 25)	Group M (n = 25)	Group R (n = 25)	x2	P-value	
3 (12.0)	0 (0.0)	2 (8.0)	3.000	0.223	
6 (24.0) ^A	4 (16.0) ^{AB}	0 (0.0%) ^B	6.462	0.040	
	Group O (n = 25) 3 (12.0)	Group O Group M (n = 25) (n = 25) 3 (12.0) 0 (0.0)	Group O Group M Group R (n = 25) (n = 25) (n = 25) 3 (12.0) 0 (0.0) 2 (8.0)	Group O (n = 25)Group M (n = 25)Group R (n = 25)x23 (12.0)0 (0.0)2 (8.0)3.000	

Data presented as n (%); The small alphabets show the value is significantly different at P < 0.05

Table 4: Comparison between groups as regards globe and lid akinesia.						
Globe and lid akinesia	Group O (n = 25)	Group M (n = 25)	Group R (n = 25)	H-test value	P-value	
At 2.5 min	8 (7-9) ^A	8 (7-9) ^A	6 (5-7) ^в	26.322	< 0.001	
At 5 min	5 (4-6) ^A	4 (4-5) ^B	3 (3-4) ^C	29.617	< 0.001	
At 7.5 min	3 (2-3-) ^A	2 (2-3) ^B	1 (1-1.5) ^C	33.143	< 0.001	
At 10 min	1 (1-2.5) ^A	1 (0.5-2.5) ^A	0 (0-0) ^B	25.437	0.022	
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Data presented as Median (IQR); P < 0.05 was considered as significant; The small alphabets show the value is significantly different at P < 0.05

Corneal Anesthesia	Group O (n = 25)	Group M (n = 25)	Group R (n = 25)	x2	P-value
At 2.5 min	8 (32.0)	19 (76.0)	17 (68.0)	11.327	0.003
At 5 min	19 (76.0)	22 (88.0)	21 (84.0)	1.303	0.521
At 7.5 min	24 (96.0)	25 (100.0)	25 (100.0)	2.027	0.363
At 10 min	25 (100.0)	25 (100.0)	25 (100.0)	0.000	1.000

corneal anesthesia and need for supplementary injections but it does not significantly fasten the onset of the block and hence the time required to start surgery.

Previous studies have analyzed adding magnesium sulphate and/or rocuronium to the local anesthetic combination in the peribulbar nerve block but with different doses or different technique from our study.

In the current prospective double-blind randomized study, our goal was to compare the effect of adding magnesium sulfate (50 mg) versus rocuronium (0.06 mg/kg) added to 9 ml of the standard local anesthetics mixture (4.5 ml of 2% lidocaine hydrochloride + hyaluronidase 150 U + 4.5 ml of 0.5% bupivacaine) for peribulbar nerve block. We assessed the effect on the time of start of corneal anesthesia and lid and globe akinesia.

Our study found significantly more rapid onset of action (mean time to start surgery) in rocuronium group than control group and magnesium sulfate group respectively, (P < 0.001). No difference was noted between control group and magnesium sulfate group. No difference was reported regarding duration of surgery between the groups. Similarly, Hamawy and Bestarous⁵ study claimed that in the rocuronium group, the time to begin surgery was shorter [7 (6–8) min], which was shown to be statistically significant in relation to both other groups; magnesium sulphate group [9 (7.5–10)] and control group [9 (8–11)], their research revealed no advantages for magnesium sulphate in terms of the time of onset of the block.

AbdAlali et al. compared the safety and effectiveness of using magnesium sulfate versus rocuronium versus dexmedetomidine as an additive to local anesthesia in peribulbar nerve block.⁶ They found that there was a statistically significant difference in the onset of motor block between the four groups. The rocuronium group demonstrated a quicker onset of motor block at 2.5 min, followed by the dexmedetomidine group, the magnesium group, and finally the control group. But their results differ from our results regarding magnesium sulphate as they found significant rapid onset in magnesium group than control group

Our findings regarding magnesium group contradicted the findings of a study by Abd El-Hamid,⁷ who demonstrated that co-administration of magnesium as an adjunct to a local anesthetic mixed in peribulbar nerve block produces rapid onset of anesthesia with no side effects. Bilir et al.⁸ found that the epidural block's start and establishment times with bupivacaine are shortened when magnesium sulfate was used as an additive.

Sinha et al. found that adding 50 mg magnesium sulfate to a solution of lidocaine hydrochloride 2% and bupivacaine 0.5% in peribulbar nerve block for ocular operations hastened the start of anesthesia and decreased the time needed to begin surgery without causing any negative side effects.¹

Regarding hemodynamic changes in our study; the three groups did not report significant differences in the pulse rate, MAP, and SpO₂, in the overall time of surgery (P > 0.05). AbdAlali et al.⁶ also reported no significant differences in hemodynamic parameters between the groups. Our results also concur with the research performed by Hamawy and Bestarous,⁵ as both rocuronium and magnesium sulfate did not cause any complications. The side effects mentioned in Hamawy and Bestarous⁵ study were attributed to the peribulbar nerve block itself, like bruising at the site of injection and mild sub-conjunctival bleeding.

Regarding globe and lid akinesia; rocuronium group showed significantly better results in 2.5, 5, 7.5 and 10 min after injection, than both control and magnesium sulfate groups; the magnesium sulfate group showed better results than the control group only at 5 min and 7.5 min. In agreement with the results of Hamawy and Bestarous,⁵ rapid akinesia and a quicker surgery was attained with rocuronium than adding magnesium to the same mixture.

Other researchers also demonstrated that magnesium sulphate and control groups performed worse on akinesia tests than the rocuronium group, which also outperformed the dexmedetomidine group. The fact that the rocuronium group required less supplementary injection served as additional evidence for decreased frequency of consequences that could be linked to repeated procedures.^{6, 9,10}

Atef and El-Kassaby¹¹ concluded that 3, 5, and 10 min after injection, the rocuronium group had significantly higher scores of lid akinesia than the control group. Additionally, the rocuronium group outperformed the control group in terms of globe akinesia scores at 5 and 10 min after injection. In studies by Sinha et al. and Abd El-Hamid, in the first 10 min following the block, the start of eyelid and globe akinesia was considerably quicker in the magnesium sulfate group than in the control group. At 15 and 20 min, there was no relevant difference between the two groups. At 20 min, the peribulbar block in both patient groups was satisfactorily complete.^{1,7}

In the present study; the rocuronium group did not need any supplemental injection. However, only 16% in magnesium group and 24% in control group need supplemental injection with significant difference between groups. Our findings were in harmony with Hamawy and Bestarous study,⁵ where the need for additional injection required by the rocuronium group was much lower, followed by magnesium sulfate and then control group. Rocuronium group's lower need for supplemental injection had an important role in lowering the incidence of complications that could be related to repeated injection, like hemorrhage and rupture of the globe.

Regarding Aissaoui et al.⁹ study, supplemental injections were needed in 4 cases (13%) in rocuronium group versus 12 cases (40%) in control group (P = 0.039). Atef and El-Kassaby¹¹ illustrated that the supplementary injection was necessary only due to an insufficient akinesia (failure of the block) in 4 cases of rocuronium group compared with 12 cases of control group (40%) representing statistically significant difference of rocuronium versus control group that required additional local anesthetic volume. On the contrary, Sinha et al. reported none of the patients experienced.

In our study at first 2.5 min; corneal anesthesia showed significantly more rapid start of sensory block, that was better in magnesium sulfate group 19 (76.0%) and rocuronium group 17 (68.0%) than in control group 8 (32.0%). However, in the subsequent 10 min, no discernible difference between the three groups was found. AbdAlali et al.⁶ showed that at 2.5 min, the dexmedetomidine group showed faster start of sensory blockade (80.0%), magnesium group (76.0%), and rocuronium group (68.0%) than the control group (32.0%). No statistically significant difference was reported regarding corneal anesthesia in Hamawy and Bestarous study as all groups reported no pain but they assessed pain at 10 min only.⁵

In our study, for addition to the local anesthetic combination a dose of 0.06 mg/kg rocuronium was chosen as it represents 10% of the standard intubation dose so believed to be safe.¹²

5. CONCLUSION

During cataract surgery, adding rocuronium to the local anesthetic combination in the peribulbar nerve block

improves ocular akinesia and corneal anesthesia and lessens the need for additional injections with no side effects. It is significantly better than magnesium sulfate in terms of rapid onset and time needed to achieve satisfactory conditions to begin surgery. Magnesium sulfate showed good results regarding akinesia, corneal anesthesia and need for supplementary injections, but it did not significantly fasten the onset of block and hence the time to start surgery.

6. Ethical clearance

This study was approved by the medical school's research ethics committee at Ain Shams University. (FMASU MD 267/2018 /2019/2020/2021/2022) with the PACTR202301561099017 identification from the Pan African Clinical Trial Registry.

7. Availability of data

upon the main author's reasonable request, all the data are available.

8. Competing interests

The authors declare that there were no conflicting interests.

9. Funding

No funding facility provided any specific funding.

10. Authors' contribution

MN: Conduction of the study work.

SAE: Manuscript editing

ME: Statistical analysis and review

AH, MR: Literature search

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