ORIGINAL ARTICLE

Effects of local low-dose rocuronium on the quality of peribulbar anesthesia for cataract surgery

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ABSTRACT

Objectives: Peribulbar anesthesia is associated with delayed and/or incomplete orbital akinesia compared with retrobulbar anesthesia. This study examined the effects of adding rocuronium 5 mg to two different concentrations of lidocaine–bupivacaine mixture on onset time of orbital and eyelid akinesia in patients undergoing cataract surgery. **Methods:** In a double-blind study, 90 patients were equally randomized to receive a mixture of 0.5 ml normal saline, 4 ml lidocaine 2%, and 4 ml bupivacaine 0.5% (group I), a mixture of rocuronium 0.5 ml (5 mg), 4 ml lidocaine 2%, and 4 ml bupivacaine 0.5% (group II), or a mixture of rocuronium 0.5 ml (5 mg), 4 ml lidocaine 1%, and 4 ml bupivacaine 0.25% (group III). Orbital akinesia was assessed on a 0–8 score (0 = no movement, 8 = normal) at 2 min intervals for 10 min. Time to adequate anesthesia was also recorded. Results are presented as mean ± SD. **Results:** Ocular movement score decreased during the assessment period in all groups. However, at 2 min after block administration, the score decreased to 4 ± 2 (95% CI 3,5) in groups II and III compared with 5 ± 2 (95% CI 4,6) in group I ($P < 0.01$). Time to adequate condition to begin surgery was 9.8 ± 2.9 vs. 6.9 ± 4.1 vs. 7.9 ± 3.9 min for groups I, II, and III, respectively ($P = 0.01$). **Conclusion:** The addition of rocuronium 5 mg to a mixture of lidocaine 2% and bupivacaine 0.5% shortened the onset time of peribulbar anesthesia in patients undergoing cataract surgery without causing adverse effects.

Key words: *Anesthetics, anesthetic techniques, bupivacaine, cataract extraction, eye movements, lidocaine, local, peribulbar, regional, rocuronium*

INTRODUCTION

Peribulbar anesthesia is widely used for cataract surgery. This technique is associated with fewer serious complications compared with retrobulbar anesthesia.[1] However, it has the disadvantage of a slow onset of orbital akinesia[2] and the frequent need for block supplementation.[3] To overcome these limitations, many adjuvant drugs[4-6] such as adrenaline, sodium bicarbonate, and hyaluronidase have been added to the local anesthetic mixture used for peribulbar block in order to augment its efficacy and hasten its speed of onset; however, their effects have been variable. Neuromuscular blocking drugs, such as vecuronium[7] and atracurium,[8] have also been added to the local anesthetic mixture and have been shown to improve the quality of peribulbar anesthesia. Atracurium, however, has histamine-releasing property and could result in undesirable local hyperemia. Rocuronium, on the other hand, is devoid of this adverse effect, has a faster onset of action, and its effects in a low dose on the quality of peribulbar anesthesia (onset time and need for supplemental injection with lower concentration of local anesthetics) have not been fully explored. Therefore, a randomized, double-blind, placebo-controlled study was undertaken to determine the effects of adding rocuronium 5 mg to two different concentrations of lidocaine and bupivacaine mixture on orbital akinesia in patients undergoing cataract surgery under peribulbar anesthesia. We hypothesized that the addition of low-dose rocuronium to the local anesthetic mixture would decrease block onset time and the need for supplemental local anesthetic injection, and would also decrease the local anesthetic concentration required for adequate anesthesia, which in turn would decrease the inherent risk of local anesthetic toxicity.

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METHODS

After institutional Ethics Committee approval, written informed consent to participate in this randomized double-blind study was obtained from 90 American Society of Anesthesiologists' physical class II–III patients scheduled for elective cataract surgery under peribulbar anesthesia. Patients were considered for inclusion in the trial if they were 18–80 years of age, and were excluded if they had any of the following: Severe uncontrolled hypertension, orthopnea, abnormal bleeding tendencies, difficulty in communication, extra-ocular muscles or eyelid abnormalities, allergy to any of the study drugs, and/or the presence of any contraindication to peribulbar anesthesia. Using a computer-generated randomization schedule and serially numbered, opaque, sealed envelopes, patients were randomly allocated to one of three study groups. Group I received peribulbar anesthesia using a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, and 0.5 ml normal saline. Group II received a mixture of 4 ml lidocaine 2%, 4 ml bupivacaine 0.5%, and 0.5 ml rocuronium (5 mg). Group III received a mixture of 4 ml lidocaine 1%, 4 ml bupivacaine 0.25%, and 0.5 ml rocuronium (5 mg). Medications were prepared in pharmacy in a 10-ml syringe labeled as "study drug" to maintain blinding. All physicians, patients, nursing staff, and data collector were blinded to the patient group assignment.

Prior to performance of the block, a blinded observer evaluated the patient's eyelid and ocular movement at the site of surgery. Standard monitors were attached and oxygen was administered at 2 l/min via nasal prongs. Peribulbar anesthesia was performed, as described by Fry and Henderson,[9] by the same anesthesiologist who was blinded to the local anesthetic drug used, without sedation. In brief, a 27-guage, 12-mm needle was used to inject 0.5 ml of lidocaine 0.2% through the conjunctiva and infra-temporally just posterior to the inferior tarsal plate to anesthetize the conjunctiva. After 15 seconds, an infra-temporal trans-conjuctival injection of the study drug (4.25 ml) using a 25-gauge, 25-mm needle was performed followed by gentle massage for 30 seconds to facilitate the spread of the local anesthetic mixture. A second trans-conjuctival injection of the study drug (4.25 ml) was performed medial to the lacrimal caruncle. Injection of the intended volume of the study drug was stopped when there was fullness of the orbit and/or drooping of the upper eyelid during injection. A Honan's cuff was immediately applied to the eye afterward and inflated to 30 mmHg for a total of 10 min. During this time, the cuff was deflated every 2 min to assess ocular movements and the orbicular muscle. Corneal anesthesia was also evaluated using a small cotton wool at the same time intervals. To assess ocular akinesia, patients were asked to look in four directions: Lateral, medial, superior, and inferior. Ocular movement in each direction was scored as 2 if it was normal, 1 if it was limited, and 0 if there was no directional movement (total score 0–8).[10] The patient was then asked to forcefully close his/her eyes to assess the orbicularis muscle on a scale of 0–2 (0 = complete akinesia, 1 = partial movement, 2 = pronounced movement).[4]

Time to adequate condition to begin surgery (defined as the presence of corneal anesthesia together with ocular movement score ≤1 and eyelid squeezing score of 0) was recorded using a stopwatch. If adequate condition to begin surgery was not obtained 10 min after performing the block, supplemental injection with 2 ml of lidocaine 2% either inferotemporally or medially was administered based on the anesthesiologist's assessment. At the end of surgery, all patients were asked to rate their intraoperative pain using a visual analogue scale (VAS) with two anchor points; 0 being no pain and 10 being the worst imaginable pain. All adverse events including the presence of diplopia and/or ptosis were recorded.

Statistical analysis

Based on a two-sided alpha of 0.05, 95% power, a population variance of 2, and a clinically relevant difference in ocular movement score of 2, a minimum of 81 patients were required for the conduct of the study. All analyses were performed on an intention to treat basis. Continually measured data were analyzed using repeated measures analysis of variance, and non-continuous data using analysis of variance. *Post hoc* pairwise comparisons were performed, when appropriate, using Tukey's test. Proportions were analyzed with Chi-square test. All statistical procedures were performed using SPSS® statistical package (SPSS Inc., Chicago, IL, USA), version 16.0 for Windows® except for sample size calculation which was performed using PS Power and Sample Size Calculations Program®, version 2.1.31 (Copyright © 1997 by WD Dupont and WD Plummer). Results are presented as mean±SD, unless otherwise indicated, and statistical significance was defined as $P<0.05$.

RESULTS

A hundred patients met the inclusion criteria and were approached for participation in the study; however, only 90 gave written informed consent to participate, were randomized in equal numbers to three study groups, were analyzed in their respective group, and had no protocol violations. Baseline characteristics were similar amongst the three study groups [Table 1]. At 2 min after peribulbar

block, ocular movement score [Figure 1a] and eyelid squeezing score [Figure 1b] were both lower in groups II and III compared with group I ($P<0.01$ for F-test of between-subjects effects); however, both the scores decreased during the assessment period in all study groups [Figure 1] ($P<0.01$ for F-test of within-subjects effects). There were no differences between groups II and III with regard to ocular movement and eyelid squeezing scores (P=NS, Tukey's test). In contrast, corneal anesthesia was achieved at 2 min after block administration in over two-thirds of the patients in groups I and II compared with only a third of those in group III [Table 2] ($P<0.01$). However, this difference disappeared by 4 min, and by 8 min all study patients except for one in group II had achieved corneal anesthesia [Table 2] (P=NS). Time to adequate condition to begin surgery was significantly shorter in group II compared with group I ($P<0.01$, Tukey's test) [Table 1], but there was no difference between groups II and III (P=0.5, Tukey's test) or I and III (P=0.1, Tukey's test). About 20–30% of the study patients required supplemental local anesthetic injection (P=0.67) [Table 1].

At the end of surgery, all study patients had similar rating for their intraoperative VAS scores (2.3±1.3 vs. 2.2±1.9 vs. 2.3±2.1 for groups I, II, and III, respectively; P=0.9).

Conjunctival ecchymosis was observed in 6 (20%) patients in group I, 8 (27%) in group II, and 5 (17%) in group III (P=0.63). Non-threatening small periorbital hematoma occurred only in one patient in group III (P=NS), was controlled by gentle pressure, and did not result in cancelling the operation. Postoperative ptosis was seen in two patients; one in group I and another in group II (P=NS); however, both patients recovered in a week time. None of the study patients had diplopia on postoperative follow-up 24 hours after surgery.

Table 1: Patients' characteristics

Variable	Group I (*n*=30)	Group II (*n*=30)	Group III (*n*=30)	*P* value for ANOVA
Age (years)	60±9	59±11	61±8	
Weight (kg)	68±11	67±10	67±14	
ASA (II/III)	20/10	21/9	18/12	
Gender (male/female)	17/13	16/14	14/16	
Orbital axial length (mm)	24±1	24±1	24±1	0.32
Local anesthetic volume (ml)	8.9±2.1	8.5±2.1	8.6±2.4	0.78
Type of surgery				-
Phacoemulsification	28	26	28	
Extra capsular extraction	2	4	2	
Time to adequate condition to begin surgery (min)	9.8±2.9	6.9±4.1*	7.9±3.9	0.01
Duration of surgery (min)	29±8	28±10	31±14	0.57
Supplemental injection (n)	9 (30%)	6 (20%)	7 (23%)	0.67

Group I = Lidocaine 2% + bupivacaine 0.5%; Group II = Lidocaine 2% + bupivacaine 0.5% + rocuronium 5 mg; Group III = Lidocaine 1% + bupivacaine 0.25% + rocuronium 5 mg; data shown as mean±SD or absolute numbers (%). ASA = American society of anesthesiologists. *P<0.01 (Tukey's test), different from group I only

Table 2: Onset time of corneal anesthesia

Corneal anesthesia present at	Group I (*n*=30) (%)	Group II (*n*=30) (%)	Group III (*n*=30) (%)	*P* value for Chi-square (%)
2 min	21 (70)	23 (76.7)	10 (33.3)*	<0.01
4 min	24 (80)	25 (83.3)	22 (73.3)	0.72
6 min	30 (100)	29 (96.7)	28 (93.3)	0.77
8 min	30 (100)	29 (96.7)	30 (100)	0.99
10 min	30 (100)	29 (96.7)	30 (100)	0.99

Group I = Lidocaine 2% + bupivacaine 0.5%; Group II = Lidocaine 2% + bupivacaine 0.5% + rocuronium 5 mg; Group III = Lidocaine 1% + bupivacaine 0.25% + rocuronium 5 mg; data shown as absolute numbers (%). *Different from groups I and II

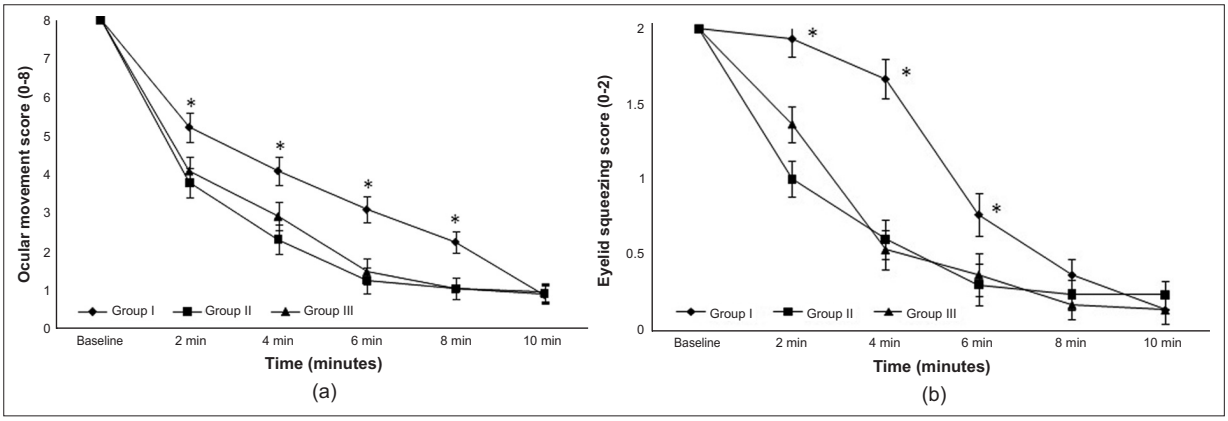

Figure 1: Orbital movement scores (a) and eyelid squeezing score (b) during the first 10 min after peribulbar block administration. Group I, lidocaine 2% + bupivacaine 0.5% + saline; group II, lidocaine 2% + bupivacaine 0.5% + rocuronium 5 mg; group III, lidocaine 1% + bupivacaine 0.25% + rocuronium 5 mg. Data presented as mean±SEM. Within 2 min after block administration, orbital and eyelid scores decreased in all the groups (P<0.01) but were more pronounced in groups II and III compared with group I (P<0.01). By 10 min, all the groups had similar scores (P=NS)

DISCUSSION

This randomized, double-blind study showed that the addition of rocuronium 5 mg to a mixture of lidocaine and bupivacaine provided adequate peribulbar anesthesia and decreased its onset time in patients undergoing cataract surgery. In addition, the use of a mixture of lidocaine 2% with bupivacaine 0.5% gained an average of 2 min in time to adequate condition to begin surgery compared with a mixture of lidocaine 1% and bupivacaine 0.25%; however, this difference did not achieve statistical significance.

Although ocular movement scores in patients who received rocuronium (groups II and III) decreased by 50% at 2 min after block administration, the onset of corneal anesthesia was slow in group III compared with group II. This is most likely related to the use of a dilute local anesthetic solution (lidocaine 1% and bupivacaine 0.25%) in the latter group which needed more time to work. In support of this is the fact that the proportion of patients who achieved corneal anesthesia at 4 min was similar in all groups. The minor delay in corneal anesthesia onset time in group III did not have a significant effect on the time to adequate condition to begin surgery or on orbital and eyelid akinesia.

The use of a lower concentration of local anesthetics for peribulbar anesthesia could be advantageous since this block usually requires a large volume of local anesthetic[9] and there is a frequent need for block supplementation.[4] In the current study, a mixture of lidocaine 1%, bupivacaine 0.25%, and rocuronium 5 mg was as effective as a mixture of lidocaine 2% and bupivacaine 0.5% with or without rocuronium in achieving orbital and eyelid akinesia albeit at different onset times. Furthermore, the need for supplemental local anesthetic injection was not increased in patients who received lower concentration of local anesthetic (group III) compared with those in group II who received the usual concentration. In fact, the overall rate of supplemental injection in the current study (20–30%) was comparable with previous reports.[4,7]

The results of this study are consistent with those reported by Kucukyavuz and Arici[8] who have demonstrated that the addition of atracurium 5 mg to a mixture of lidocaine 2% and bupivacaine 0.5% improve orbital akinesia and hasten block onset time. Reah and colleagues[7] have also shown similar results when vecuronium is added to a standard mixture of lidocaine and bupivacaine, however, they have also added hyaluronidase 150 U to their local anesthetic mixture which was not the case in our study. Recently, Aissaoui and colleagues[11] have reported that the addition of rocuronium 0.06 mg/kg to a local anesthetic mixture of 2% lidocaine and 0.5% bupivacaine improves the akinesia scores. The current study differed from that of Aissaoui and colleagues by using a fixed low dose of rocuronium as opposed to a variable dose based on body weight. In addition, a lower concentration of local anesthetic mixture (1% lidocaine with 0.25% bupivacaine) was tested in the current study and was found to be effective when combined with rocuronium 5 mg.

The exact mechanism through which the local administration of a non-depolarizing muscle relaxant improves orbital and eyelid akinesia is not known, but is believed to be due to local effects at the muscles motor end-plate. In this study, the dose of rocuronium chosen was less than one-tenth the dose administered intravenously for clinical neuromuscular blockade. This was planned so that in the unlikely event of inadvertent intravascular injection during block administration, the main adverse effects would be related to the local anesthetic mixture as opposed to rocuronium itself. The other potential adverse event of peribulbar anesthesia is central spread of the local anesthetic. There are currently no data on the potential effects of a small dose of rocuronium if injected intrathecally. In this study, patients were constantly monitored in the operating room by an anesthesiologist who was prepared to intervene in the event of the remote theoretical chance of muscle weakness developing due to central spread of anesthesia.

Study limitations

Time to complete recovery of orbital and eyelid akinesia was not assessed in this study since all patients bypassed the post-anesthesia care unit and went directly to the day care unit for home discharge. Bypassing the post-anesthesia care unit for cataract surgery patients who do not receive sedation is standard practice in our institution.

In conclusion, peribulbar anesthesia using a mixture of rocuronium 5 mg, lidocaine 2%, and bupivacaine 0.5% provides optimal orbital and eyelid akinesia for cataract surgery and shortens the block onset time. However, this does not significantly decrease the need for block supplementation with local anesthesia. Although topical anesthesia for cataract surgery has become widespread, it is associated with increased patient discomfort,[12] and therefore requires a higher degree of patient's cooperation. Accordingly, the results of this study would still be applicable in those patients in whom peribulbar anesthesia is the anesthetic of choice.

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