

Efficacy and safety of ropivacaine and lidocaine in patients undergoing peribulbar anaesthesia for small incision cataract surgery

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Abstract: *Background:* Ropivacaine is found to be a suitable choice for local anaesthesia showing a short and predictable onset of surgical anaesthesia with better control of post-operative pain relief. *Objectives:* To compare the intra-operative clinical properties of 0.75% Ropivacaine and 2 % Lidocaine for small incision cataract surgery. *Methods:* Patients (n=64) undergoing cataract surgery with Posterior Chamber Intraocular Lens (PCIOL) implantation, were randomized into two groups i.e Ropivacaine group and Lidocaine group to receive peribulbar injection. Antibiotic drops were instilled in the patient's eyes a day prior to the surgery and dilating eye drops were instilled in the eye to be operated on the day of the surgery. The test dose was given to check the sensitivity followed by procedure involved for peribulbar anaesthesia. *Results:* The mean time of onset of analgesia for Lidocaine group is 118.13±60.93 seconds whereas for Ropivacaine group is 60.94±36.93 seconds. The mean time of onset of akinesia for Lidocaine group is 237.19±87.67 seconds whereas for Ropivacaine group is 183.75±89.76 seconds. The median of analgesia (p<0.0001) and akinesia (p=0.0294) was significantly higher for Lidocaine group than Ropivacaine group. *Conclusion:* 0.75% Ropivacaine has better analgesic and akinesia effect than Lidocaine group for small incision cataract surgeries.

Keywords: Akinesia, Analgesia, Intraoperative Procedures, Lidocaine, Ropivacaine

Introduction

Safer surgical techniques have been followed with a need for safer techniques of anaesthesia [1]. For a simple and trouble-free cataract surgery, various approaches are used for anaesthesia technique e.g. topical anaesthesia, retrobulbar and peribulbar anaesthesia with various anaesthetics in different combinations.

Generally, the retrobulbar anaesthesia and peribulbar anaesthesia are the standard local anaesthesia (LA) techniques for cataract surgery because it gives good analgesia and akinesia [2-3]. Posterior peribulbar anaesthesia is a safer alternative to retrobulbar anaesthesia for ophthalmic surgery. Retrobulbar anaesthesia has high margin of error with its adverse effect being retrobulbar haemorrhage, globe rupture or inadvertent entry into cranial cavity. To enhance the permeability and spread of anaesthesia, adjuvants or additives are used such as hyaluronidase, epinephrine, bicarbonates etc.

Hyaluronidase improves spread of solution in tissue planes enhancing the effect of the anaesthesia because of its depolymerising and hydrolysing action on the glycosaminoglycan, hyaluronan.

LA agents namely lidocaine, bupivacaine, mixture of both lidocaine and bupivacaine and ropivacaine are commonly available. Bupivacaine is very often used as the local anaesthetic for peribulbar block. Ropivacaine is a new long-acting aminoamide local anaesthetic that is structurally related with bupivacaine [4]. Furthermore, Lidocaine is known for its fast onset and good penetrating properties [5]. A mixture of lidocaine and bupivacaine may lead to the reduction of advantages of both the agents [6].

Till now there is no consensus regarding the best anaesthetic agent that can be used during cataract surgery. Some studies have reported

that Ropivacaine may be a suitable choice for LA because of its favourable cardiovascular, neurologic, pharmacological profile and also for better quality of post-operative analgesia with decreased incidence of post-operative subconjunctival haemorrhage [7-10]. In the current study, two anaesthetic agents (Lidocaine and Ropivacaine) are compared for the intra-operative clinical properties for small incision cataract surgeries.

Material and Methods

A comparative randomized controlled study was conducted in a tertiary care hospital setting and a medical research centre under the department of ophthalmology from August 2018 to February 2019. The study was approved by the institutional ethics committee on Human Subject Research.

Study Population: Total 64 patients were enrolled to receive peribulbar injection. Patients aged ≥ 18 years and recommended to undergo a cataract surgery with Posterior Chamber Intraocular Lens (PCIOL) implantation and were recruited based on the inclusion criteria. Patients with pre senile and senile immature cataract, senile mature cataract, hyper mature cataract, traumatic cataract and having no previous history of intraocular surgery were study inclusions. Whereas the patients excluded from the study include those having congenital cataract, associated systemic disease and hypersensitivity to the drug.

Randomisation and masking: A computer-generated randomisation list was used for random allocation sequence. The patients were masked to the type of agent. All the peribulbar blocks were done by the same resident surgeon.

Sample Size: We took into account the time of onset of anaesthesia and akinesia results of a previous study [8]. Sample size calculation was carried out using a two-sided two-sample t-test. The power analysis was carried out based on the onset of anaesthesia and akinesia, which were the primary outcomes. Sample size of 32 patients per group would achieve an 80% power with estimated means of 2.14 and 3.04 and with estimated group SDs of 0.18 and 1.81 and with a significance level (α) of 0.05.

Study Procedure: Eligible patients were randomly divided into two groups. Informed

consent was taken from all the patients prior to the initiation of the study. The groups received not more than 10 ml of 2% lidocaine with 75 units hyaluronidase or 0.75 % of ropivacaine with 75 units hyaluronidase. On the day prior to surgery, a thorough history of the patients was noted, complete ophthalmic evaluation and routine laboratory investigations were performed and duly filled in the proforma. On the day of surgery, test dose of the drug was given to check for sensitivity followed by peribulbar anaesthesia where a 26-gauge 0.5-inch disposable needle was used.

The sites of injection were chosen between medial 2/3rd & lateral 1/3rd of lower orbital margin adjacent to infraorbital notch or just infero-medial to supra orbital notch or between medial canthus & caruncle or all three. The bevel of the needle was directed towards globe and advanced parallel to orbital floor with no redirection as in retrobulbar block. Hub of the needle was not supposed to cross the inferior orbital rim. After negative aspiration for blood, 4 to 5ml of local anaesthetic agent was injected.

Administration of the local anaesthetic was stopped when either firmness of the globe or resistance was felt. After injection, the globe was massaged with the index and middle fingers placed over a sterile gauze pad. Gentle pressure was applied over the eyeball for 2 minutes. Pressure was released for 5 seconds at 30 second intervals to allow for vascular pulsations to occur. At the end of the second minute, a second injection infero medial to supraorbital notch-peribulbar block or medial-peribulbar block was administered using the same 26-gauge 0.5-inch disposable needle to a depth of 15 to 20 mm.

After the second injection, the globe was massaged again using gentle pressure. A total volume of not more than 10 ml local anaesthetic solution was used. The efficacy of the block was evaluated for every 30 seconds till 300 seconds. Modified visual analog scale [11] for subjective assessment was used and cotton swab test was performed for objective assessment to check the adequacy of analgesia. Sensory blockade was graded as

achieved-1, not achieved -2. Adequacy of akinesia was assessed using the scoring system specified in a study conducted by Bhrama et al [12]. Full movements were graded as 3, moderate movement as 2, flicker movement as 1, and no movement as 0. Ocular movements were scored for each direction of gaze in the superior, inferior, medial and lateral directions, with a possible maximum score of 12 points. Adequacy of anaesthesia was assessed by considering the onset of anaesthesia and akinesia which was graded for every 30 second interval and noted.

If adequate analgesia and akinesia was not achieved after 5 minutes, a supplementary injection either at the inferolateral quadrant or medial peribulbar site using 3 to 5 ml of the test solution was given. Patients were asked to communicate with the surgeon regarding pain if experienced during or after surgery. Pain during surgery was recorded as nil-0, mild-1, mod-2, severe-3. After surgery, the surgeon graded the efficacy of anaesthesia from 0 to 5 [13].

Statistical Analysis: The data was summarised as mean ± SD for continuous variable and categorical variables using Ri386 3.5.1 statistical software which were represented using percentages. The comparison between the groups was done using independent t-test/ Mann Whitney U-test. Categorical variables between 2

groups were compared by using the chi-square/Fisher exact test. P<0.05 is considered as significant.

Results

The mean time of onset of analgesia for Lidocaine group was 118.13±60.93 seconds whereas for Ropivacaine group was 60.94±36.93 seconds (sec). The mean time of onset of akinesia for Lidocaine group was 237.19± 87.67 sec whereas for Ropivacaine group was 183.75±89.76 sec. We conclude that median of analgesia (p<0.0001), as well as akinesia (p=0.0294), was significantly more for group A than group B (figure 1). There is no significant association between adequacy of blocks and anaesthetic agents as only 12.5% individuals in lidocaine group needed supplementary injection as compared to nil for Ropivacaine group.

Almost 100% patients in both groups were graded 5 for efficacy. There was no significant association between subconjunctival haemorrhage and the anaesthetics used whereas there was an association between chemosis and anaesthetic agent. Hence, we observed that in both the groups, none of the subjects had the problem of diplopia (Figure 1 and Table 1).

Fig-1: Comparison of analgesia and akinesia between 2 groups

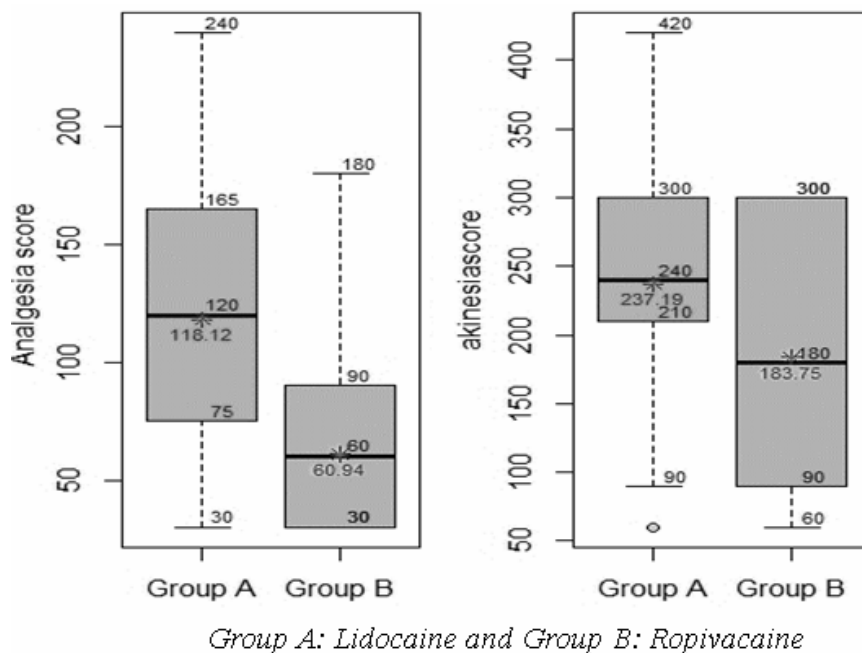


Table-1: Comparison of different factors between 2 groups				
Variables		Group A	Group B	P-value
		Mean ± SD	Mean ± SD	
Analgesia (Seconds)		118.13 ± 60.93	60.94 ± 36.93	#<0.0001*
Akinesia (Seconds)		237.19 ± 87.67	183.75 ± 89.76	#0.0294*
Block sufficient	Yes	28 (87.5%)	32 (100%)	0.1132 ^a
	No	4 (12.5%)	0	
Sub conjunctival haemorrhage	Yes	2 (6.25%)	0	0.4921 ^a
	No	30 (93.75%)	32 (100%)	
Chemosis	Yes	11(34.38%)	0	0.0009 ^{aa*}
	No	21 (65.62%)	32 (100%)	
Diplopia	Yes	0	0	-
	No	32(100%)	32 (100%)	
<i>^a indicates Fisher exact test; ^{aa} indicates chi-square test; # indicates Mann-Whitney U-test Group A: Lidocaine and Group B: Ropivacaine</i>				

Discussion

The characteristics of an ideal peribulbar anaesthetic agent are safety, ease of administration, efficacy of ocular akinesia and anesthesia with least complications. In our study the clinical properties of 0.75% ropivacaine and 2% lidocaine was compared to assess their analgesia and akinesia intraoperatively.

Our study shows a better analgesia property in the group receiving 0.75% Ropivacaine of approximately 1 minute than the group which received 2% Lidocaine of approximately 2 minutes. Onset of akinesia was faster in the group receiving 0.75% Ropivacaine group of approximately 3 minutes compared to the 2% Lidocaine of approximately 4 minutes. Ropivacaine had a quicker onset and prolonged effect [9]. Ropivacaine with 94% plasma protein binding capacity has longer duration of action as compared to lidocaine with 64%, justifying the need for supplemental injection in 12.5% individuals of that group. Therefore, we firmly believe that ropivacaine is able to sustain analgesia during a longer operation time in peribulbar block.

It is known that retrobulbar injection gives a more prominent block of the nerves but it has its own limitations. Peribulbar injection can overcome

these limitations by keeping the sharp needle away from the orbital apex. With minimal complications cataract surgery is one of the commonest surgeries performed under local anaesthesia. However, there are some cases of post-operative complications eg. sub conjunctival haemorrhage (SCH), chemosis, diplopia. In our study, none of the subjects in ropivacaine group had the above mentioned complications. Out of 32 subjects in the lidocaine group 2 had sub conjunctival haemorrhage, 11 had chemosis but none of them suffered from diplopia. In the postoperative period significant number of patients attained grade 5 block in Ropivacaine group than in Lidocaine group. Also, time of onset of pain was observed to be earlier in lidocaine group than in ropivacaine group.

Limitation of the study: Our study concluded that Ropivacaine is the ideal anaesthetic agent for cataract surgery by covering all the factors linked to it. As a post-operative practice, we cover the operated eyes with a sterile gauze pad and remove it the next day. We didn't make an exception where the post-operative anaesthesia was being observed, this posed a minor limitation to the study as the exact time for termination of sensory and motor blockade could not be ascertained.

Conclusion

Ropivacaine has better analgesic as well as akinesia effect as compared to Lidocaine. This indicates that Lidocaine induces lesser pain bearing capacity than Ropivacaine. The akinesia effect was found to have faster onset in

Ropivacaine group than in Lidocaine, which means that movement of the muscles were more impaired in Ropivacaine group. It can be inferred that 0.75% Ropivacaine is better than lidocaine under the same standard conditions.

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