COMPARISON OF ROLE OF SODIUM BICARBONATE (7.5%) AS AN ALTERNATIVE OF HYALURONIDASE IN OCULAR ANAESTHESIA FOR CATARACT SURGERY

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ABSTRACT: PURPOSE: To compare the safety, efficacy and cost effectiveness of sodium-bicarbonate mixed anesthetic mixture with hyaluronidase mixed mixture in peribulbar anesthesia for cataract surgery. **MATERIAL AND METHOD:** This prospective study was conducted on 50 patients admitted for cataract surgery in Department of Ophthalmology, U. P. Rural Institute of Medical Sciences and Research, Saifai, Etawah. They were randomly and equally divided into two groups and received one of the anesthetic mixtures for peribulbar anesthesia. **RESULTS:** Results were analyzed according to systemic effects (blood pressure, pulse rate), local effects (conjunctival congestion, chemosis, lid edema, and intraocular pressure), time of onset of anesthesia, and its duration and cost burden. **CONCLUSION:** The study implied that there is clear picture which could be seen that sodium bicarbonate mixture is equally safe, equally effective and less costly as compared to hyaluronidase mixture.

KEYWORDS: Sodium bicarbonate, Hyaluronidase, Peribulbar anesthesia.

INTRODUCTION: Local anesthesia is the most common form of anesthesia used for the patient undergoing cataract surgery. There are several different techniques and solutions which have been used for local anesthesia; but the main aims are safety, reduction of onset of time, prolongation of duration of action, easily availability and less costly.

This study evaluates the safety, efficacy and cost effectiveness of 7.5% sodium bicarbonate buffered mixture of 2% Xylocaine and 0.5% Bupivacaine with hyaluronidase mixed solution. Since peribulbar anesthesia is safer than retrobulbar anesthesia, so in this study we used peribulbar anesthesia.

MATERIALS AND METHODS: This prospective study was conducted on 50 patients admitted for elective surgery in Department of Ophthalmology U.P. Rural Institute of Medical Sciences and Research, Saifai, Etawah. Our 700 bedded institutes is one of the premium government institutes in rural setup of North India region. A written consent and detail history of all patients were taken. Thorough general and systemic examination followed by detail ocular examination was done. Routine investigations were also done. Patients with refusal for consent, known allergy to any component of anesthetic mixture, children, and mentally retarded, uncooperative, asthmatic, hypertensive were excluded from the study. The project was approved by the institutional ethical committee.

Patients were randomized in two groups - group A and group B. Two anesthetic mixtures were prepared. Mixture A contained Lignocaine 2% with Adrenaline (1:200000) (Xylocaine 2% adrenaline -30ml vial -AstraZeneca Pharma, India Ltd.) and 0.5% Bupivacaine (Sensorcaine-20ml vial

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Astra Zeneca Pharma India Ltd.) with 7.5% sodium bicarbonate - 10ml amp (Vulcan Lab Pvt. Ltd.). This was prepared by mixing slowly drop by drop 1 ml of 7.5% sodium bicarbonate in 30 ml of anaesthetic mixture of 2% xylocaine with adrenaline and 0.5%bupivacaine (in 1:1 ratio) in about 2 minutes without shaking the bottle to prevent precipitation.

Mixture B was prepared by mixing 500 IU of hyaluronidase (1500 IU vial- hynidase-Amadeus Biotech and pharmaceuticals) with 30 ml mixture of 2% xylocaine with adrenaline and 0.5% bupivacaine (in 1:1 ratio). It makes the hyaluronidase strength near about 15IU/ml in the anaesthetic mixture.

Grading of anaesthesia and akinesia was measured at 2min, 5 min and 7 minutes as shown in table1.

Grade - 1	Grade - 2	Grade - 3	
Complete anaesthesia and akinesia demonstrated by	Anaesthesia and akinesia considered adequate for safe intra ocular surgery demonstrated by.	Unsuccessful anaesthesia and akinesia judge by	
Complete absence of eye movement.	Eye movement <15° in any direction of gaze.	Eye movement >15° in any direction of gaze.	
Complete anesthesia of conjunctiva and cornea.	Complete anesthesia of conjunctiva and cornea.	Complete/incomplete anesthesia of conjunctiva and cornea.	
Painless insertion of the superior rectus bridle suture.	Painless insertion of the superior rectus bridle suture.	Painful insertion of the superior rectus bridle suture.	
Table 1: Grading of Anesthesia and Akinesia			

Patient with grade 3 anesthesia had a supplement 2 ml injection of the same mixture by same technique. Both groups were evaluated for systemic safety variable which includes:

- a) Systolic and Diastolic B.P.
- b) Pulse rate

They were also evaluated for ocular safety variables like:

- a) IOP (by schiotze tonometer)
- b) Conjunctival congestion
- c) Chemosis
- d) Lid edema
- e) Orbital fullness
- f) Subconjunctival haemorrhage

To compare the efficacy between two groups the following points were considered:

- a) Time of onset of anaesthesia and akinesia
- b) Successful block rate/ reblock rate.

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The standard micro surgical procedure was performed as SICS with PCIOL. The procedure lasted for 20-50 minutes. All the operated patients had routine postoperative medications consisting of topical antibiotics, steroid eye drops - 4 times a day, 1% cyclopentolate eye drop once a day. On1st and 2nd post-operative days all patients were examined under slit lamp, fundus was examined with +90D lens and by direct ophthalmoscope, pinhole visual acuity was recorded and follow up examination was done at second week, fourth and sixth week in all patients.

RESULT: Out of 25 patients in group A, 24% were below 50 yrs, 64% between 50-70 yrs and12% were > 70 yrs, 64% were male, while 36% were female. In group B 16% were below 50 yrs, 76% between 50-70 yrs, and 8% were more than70 yrs, out of which 44% were male and 56% were female. The main clinically significant data was given in table II.

Sr.	Parameters	Group 'A (Mean+_SD)'	Group 'B' (Mean+_SD)
1	Change in systolic B.P. after block (In mmHg.)	5 ± 5	5.8 ± 3.1
2	Change in diastolic B.P. after block (In mmHg.)	2.16 ± 1.23	2.2 ± 1.64
3	Mean time of onset of anaesthesia (In min)	6.32 ± 1.43	6.00 ± 1.53
4	Change in IOP after block (In mmHg. of schiotze)	2.87 ± 1.63 (0 - 6.9)	3.20 ± 1.97 (0 -7.9)
5	No. of cases required additional mixture	16% (4 cases)	12% (3 cases)
6	Significant discomfort felt by the patient after injection	8% (2 cases)	4% (1 cases)
7	Immediate local complications (lid edema, chemosis, congestion)	20% (5 cases)	16% (4 cases)
8	Duration of anaesthesia (In min.)	37.6 min (30-50)	37.4 (30-50)
9	Any significant follow up complication	nil	Nil
10	Cost per patient (Rs.)	8.75	15.00
	Table 2		

Cost of different constituents were as follow:

1	Xylocaine 2% with adrenaline (30 ml)	17.00 Rs.
2	Sensorcaine 0.5% (20 ml)	35.00 Rs.
3	Hyaluronidase (1500 I U)	52.00 Rs.
4	Sodium bicarbonate (10 ml)	12.00 Rs.

DISCUSSION: It is found that local anesthetic agents (LA) are weak bases with pKa values varying from 7.7 to 8.9. Their active forms are ionized form which blocks the Na⁺ channel of nerve fibre. The blockage site is inside the cell. So they have to penetrate the cell membrane. They are supplied in acidic solution to improve stability.

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At this pH LA, agents exists mainly in ionized form which are not permeable through cell membrane causing more slow blockage than a solution with pH that more closely approximates the pKa and contains more of the non-ionized, lipid soluble form. Caution must be taken during alkalinizing of anesthetic mixture so that there is no precipitation or denaturation. The exact pH at which it occurs is not clear and values vary in the literature but it may be above pH 7.5.

In our study it was found that 7.5% sodium bicarbonate buffered anesthetic mixture was as safe and effective as hyaluronidase mixed solution and is much cheaper than the hyaluronidase one.

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