

# Phacoemulsification without preoperative topical mydriatics: Induction and sustainability of mydriasis with intracameral mydriatic solution

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## Abstract

**Aims:** Evaluating the role of intracameral solution (0.5% lignocaine and 0.001% epinephrine) in initiating and maintaining the pupillary mydriasis during phacoemulsification. The other aims were to observe the effect of surgical time, nucleus density and ultrasound time on mydriasis during procedure. **Setting and design:** The study is a prospective interventional case series. **Materials and methods:** 30 patients underwent phacoemulsification under topical anaesthesia for visual significant cataract. pupillary dilatation was achieved by intracameral irrigation of mydriatic solution. **Conclusion:** Intracamer solution of 0.5% lignocaine and 0.001% epinephrine provides rapid mydriasis which is adequate for safe phacoemulsification

**Keywords:**

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## INTRODUCTION

Modern cataract surgery either by phacoemulsification or manual small incision cataract surgery (MSICS), both require good pupillary dilatation, which at present is achieved by repeated administration of mydriatic/cycloplegic and NSAID (non-steroidal anti-inflammatory drug) eye drop. This preparation for surgery has definite disadvantages like 1 to 1.5 hour holding of patient in preparation room, contamination of the ocular surface, epithelial toxicity due to preservatives in the topical formulas and discomfort due to frequent installation of the drops. Systemic safety of these topical formulae containing beta agonists and sympatholytics is doubtful as they are known to cause a rise in blood

pressure, ataxia, dizziness, and dry mouth. Often due to noncompliance of the patient or staff there may be no dilation or poor dilatation leading to delay in start of surgery causing wastage of man hours and resources. Due to these problems there has been an attempt to search for alternatives to this repeated eye drop installation regimen. Various options like single drop installation, Ocular inserts, depot preparation of mydriatic, and intracameral irrigation of mydriatic-cycloplegic drugs have been used with comparable result. Out of these only intracameral irrigation can obviate the need of pre-operative preparation. For this purpose many drugs have been used, namely

- Lignocaine (0.75%-1%) with epinephrine 0.025% ,
- Lignocaine solution 1%
- Cyclopentolate 0.1% phenylephrine 1.5% and lignocaine 1%

We have not considered using cyclopentolate solution as studies have confirmed that the use of cyclopentolate does not enhance the action provided by intracameral lignocaine. A part from lignocaine, the other component of this intracameral mydriatic solution is sympathomimetic, for which we have two options, namely phenylephrine and epinephrine. The dual effect of epinephrine to contract the dilator musculature by its

receptor action and relax the spincter by  $\beta$  effect could act synergistically to dilate the pupil more than phenylephrine. Potential of intracameral epinephrine to cause macular edema has been studied and it has been reported that intracameral epinephrine at 0.2 mg/ml concentration of less does not increase this risk, systemic safety of intracameral epinephrine has been established in medically controlled hypertensive patients. Going by the present evidence intracameral irrigation of lignocaine with epinephrine is an effective and safe option for initiating and maintaining papillary dilatation during cataract surgery. In this study we aimed at evaluating the role of intracameral irrigating solution of 0.5% lignocaine +0.001% epinephrine in initiating and maintaining the papillary mydriasis during phacoemulsification under topical anaesthesia, without any topical mydriatic or NSAID use. Secondary aims were to observe the effect of surgical time, ultrasound time and nucleus density on sustainability of mydriasis during the procedure.

## MATERIALS AND METHODS

### Sample size

Using 1%  $\alpha$  (avoiding false positive outcome, as good pupillary dilatation is important for safe surgery), the power calculation determined that at least 18 observation were needed to reach 95% power for a mean value of 7 mm (SD 1.2) we have kept the critical value of pupil size as 6 mm for safe phacoemulsification. To enhance the reliability of our observation and to compensate for dropouts, we have taken a sample size of 30.

### Patient selection and Study Design

The study was prospective interventional case series. Patients who were planned for phacoemulsification under topical anaesthesia for visually significant cataract were screened for exclusion criteria [Table 1] and included in the study after obtaining their informed consent. Patients were not screened for Pseudoexfoliation or intake of alpha blockers; however, papillary dilatation of less than 6 mm (measured using slit lamp, with topical solution of Tropicamide 0.8%+ phenylephrine Hydrochloride 5%) was one of the exclusion criteria. Patients who had perioperative complications like iris trauma or vitreous loss during the study were to be excluded from the study. All the patients were examined with dilated pupils two days before the surgery to grade the nucleus grade using LOCS III and to verify adequate papillary dilatation (>6mm).

### Pupillary Dilatation and Surgical Technique

The mydriatic solution was prepared by injecting 2 ml of epinephrine solution (0.1% or 1:10000 into 50 ml solution of preservative free lignocaine 2% (injection Xylocard, Astra Zeneca India Ltd.) This was prepared freshly before surgery and used within 2 h of preparation, owing to degradation of epinephrine in sunlight and normalization

of pH. This solution was further diluted fourfold by mixing 0.5ml of this cocktail with 1.5 ml of BSS (Balanced Salt Solution), this achieving the final concentration of lignocaine 5mg/ml (0.5%) and epinephrine-0.01 mg/ml (0.001%) or 1:100,000). Topical anesthesia was provided by the use of lignocaine jelly 2% (Xylocain Jelly 2% Astra Zeneca India Ltd.) After making the keratome entry, anterior chamber was irrigated with the intracameral mydriatic solution. There was no specific dose of irrigating fluid delivered; the aim was to replace the aqueous with the irrigating fluid. On an average approximately 0.3 to 0.5 ml of this fluid was irrigated into the anterior chamber. After measurement of pupillary dilatation this mydriatic solution was replaced by 2% methycellulose and capsulorhexis was completed. This mydriatic solution was the only mydriatic agent used during the surgery and epinephrine was not added to the irrigating BSS used, during the phacoemulsification procedure. Phacoemulsification using direct chop technique with in the bag implanatation of foldable hydrophilic acrylic Intra Ocular Lens (IOL) (RYCF model, Intra Ocular Care Pvt. Ltd. India) using cartridge and injector through 2.8 mm incision was done.

### Pupil size Measurement

Surgical calliper having a least count of 0.5 mm was used to measure the horizontal and vertical diameter of the pupil thrice during the surgery. This was done under microscope view with monocular view using only the right eye of the observer, to avoid any parallax error. Measurement of pupil size was done at following stages during the surgery.

1. Before making the incision (undilated pupil size under the microscope illumination).
2. Thirty seconds after instillation of the mydriatic solution in the anterior chamber.
3. At the termination of the surgery after wound hydration and just before removal of the lid speculum.

### Statistical Analysis

Statistical software Medcalc ver.11.4.2.0. for windows was used to perform analysis of the observations. Descriptive analysis was done on the age distribution of the subjects. Undilated pupil size, pupil size after mydriatic solution irrigation and at the termination of surgery was compared using paired samples student t-test. Influence of the grade of nuclear sclerosis, duration of surgery and ultrasound time on the pupil size was analyzed using spearman correlation coefficient.

## RESULTS

Thirty eyes of thirty patients completed the study; there were no dropouts due to surgical complications. There were no dropouts due to surgical complications. There

were no dropouts due to surgical complications. There were 15 male patients. The age distribution of subjects was normal (D Agostino-Pearson test  $P=0.37$ ) with average age being 64.3 years (Range 40.75 SD $\pm$ 8.8). The average pupil size without any mydriasis under the microscope illumination was 2.1 mm (Range 5-9 mm SD $\pm$ 1.02) at 30 seconds time after anterior chamber irrigation with the mydriatic solution. This change was statistically significant with  $P<0.0001$  (paired samples student t-test). When compared to a test value of 7 mm (papillary dilatation required for comfortable and safe Phacoemulsification) using one sample student-t-test, was not statically significant difference ( $P=0.5$ ). At the end of surgery the average pupillary diameter was 7.0 mm (Range 3.5-9 mm SD  $\pm$  0.20) Thus, pupillary mydriasis was not only maintained throughout the surgery but rather there was an increa (0.10 mm average difference) in the size of the pupil at the end of surgery. Though this difference was statistically insignificant (paired student-t-test,  $P=0.24$ ). The pupillary dilatation achieved by the use of intracameral mydriatic solution was adequate for the entire surgical procedure which took 13 min on an average (Range 9-18 min SD  $\pm$  1.6). There was a weak positive correlation between the pupil size and the surgical duration, which was statistically insignificant (Spearman correlation coefficient 0.13,  $P=0.46$ ). Nucleus density and pupillary dilatation at the end of the procedure had weak positive correlation which was statistically insignificant (Spearman correlation coefficient 0.09,  $P=0.60$ ) Fig.1. Ultrasound time had weak positive correlation to final pupillary dilatation at the end of surgery, which was statically insignificant (Spearman correlation) coefficient 0.02,  $P=0.91$ ) Fig.2. Thus the pupillary dialation achieved by the use of inatracameral mydraiatic solution was unaffected by the duration of surgery, grade of nucleus and ultrasound time.

## DISCUSSION

Adequate pupillary dilatation and maintenance of mydriasis is important for an uncomplicated phacoemulsification. The efficacy of mydriatic solution composed of lignocaine (0.75%-1%) with epinephrine 0.025% in inducing and maintaining pupillary mydriasis during phacoemulsification has been demonstrated earlier. One percent intracameral lignocaine has been demonstrated to be safe for corneal endothelium, but as this toxicity is concentration related, Thus it can be safely presumed that using a lower concentration which can provide, effective anesthesia and mydriasis would be enhancing its' safety. In our study we have demonstrated that using 0.5% lignocaine in intracameral solution can provide adequate mydriatic effect comparable to a similar study. There are conflicting reports in literature the

corenearl endothelial toxicity of epinephrine. Experimental and clinical reports claiming safety of epinephrine solutions with concentrations ranging form 1mg/ml to 0.01 mg/ml are there, and on the other hand there are studies and cases reports caliming endothelial toxicity of epinephrine at similar concentrations. We further analyzed these antagonistic reports and found the going by the present evidence endothelial toxicity is related to the buffer capacity of the epinephrine solution, which is in turn is controlled by the concentration of the antioxidant (sodium bisulfite) as well as by the vehicle formulation and a low pH value. Thus epinephrine solution toxicity to endothelium is the by product of formulations, rather than the molecule itself. So, either an endotherlial friendly formulation or maximum dilution of available formulation (which is corneal endothelium compatible with regard to concentration and pH) appear to be the possible answers for safe use of intracameral epinephrine. Thus, use of lower concentration of lignocaine and epinephrine can enhance the safety by reducing the toxicity to intraocular structures apart from retaining all the advantages offered by intracameral mydriatic solution. Combination of epinephrine with lignocaine as an intracameral irrigation solution has many advantages apart from providing anesthesia and pupillary dilation, as it provides better duration of action and more efficacy, aids in hemostasis, and markedly reduces or eliminates risk for IFIS (Intraoperative Floopy Iris Syndrome) in eyes with risk factors such as exposure to alpha Blockers and Tamsulosin. We found that the pupillary dilatational in our study was comparable to the findings in a study done by William *et al*, using similar (but more concentrated) intracameral mydriatic solution. In that study the average pupillary dilation achieved using their higher concentration intracameral mydriatic solution was 7.1 mm  $\pm$  0.7 against our average pupillarydilatation of 6.9 mm  $\pm$  1.02. Similarly at the end of surgery the average diameter was 7.3 mm  $\pm$  0.7 and 7.0 mm  $\pm$  0.20, in their and our study respectively. This indicates a slight increases in the diameter during the surgical procedure in both studies. As the surgical time, nucleus density and ultrasound time increase for any given surgical machine they cause tissue damagne and which in turn causes releae of prostaglandins leading to pupillary miosis. Topical NSAIDs (Non-Steroidal Anti-inflammatory Drugs) are used as preoperative medication routinely to prevent this pupillary constriction. In this study we have not used any preoperative NSAID, and yet the pupillary dilatation was maintained. This is an important requirement for safe removal of lens matter and is well catered by our technique of mydriasis. There are few limitation of this study, particularly, the lack of control arm (receiving conventional preoperative topical

mydriatic regimen). However the study intended to demonstrate feasibility of this method of mydriasis with lower concentration formulation rather than demonstrate comparison to various mydriatic regimens in practice. The study demonstrates that the intracameral solution alone, containing lower concentration of lignocaine and epinephrine provides rapid mydriasis which is adequate for safe phacoemulsification with intraocular lens implantation and this mydriasis is maintained throughout the procedure. The study demonstrates that the intracameral solution alone, containing lower concentration of lignocaine and epinephrine provides rapid mydriasis which is adequate for safe phacoemulsification with intraocular lens implantation

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