

## Evaluation of efficacy of intracameral lidocaine and tropicamide injection in manual small-incision cataract surgery: A prospective clinical study

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**Purpose:** The study was conducted to evaluate efficacy of intracameral lidocaine hydrochloride 1% and tropicamide injection 0.02% for anaesthesia and mydriasis in manual small-incision cataract surgery (MSICS) and to report any adverse drug reaction. **Methods:** This was a randomized, prospective, observational study on 32 participants that took place from October 2021 to March 2022 (6 months). Patients between age group 40–75 year with nuclear sclerosis cataract and pupil diameter >6 mm in preoperative evaluation were included in the study. Patients with pseudoexfoliation, rigid pupil, senile miosis, history of uveitis, ocular trauma, recent ocular infections, with known allergy to tropicamide, all types of glaucoma were excluded from the study. **Results:** Thirty-two eyes with nuclear sclerosis cataract who underwent MSICS were studied. Fixed dose combination of 2 ml phenyl epinephrine (0.31%), tropicamide (0.02%), and lidocaine (1%) intracamerally was used for mydriasis and analgesia. More than 7 mm pupillary dilatation was achieved within 20 seconds of injection in 29 cases (90.6%). Mild pain and discomfort was noted in 12 cases (37.5%). Postoperative day 1 unaided visual acuity was in the range of 6/18–6/12 for all patients and grade 1 iritis was seen in 7 cases (21.8%) which was self-limiting. No adverse event like corneal decompensation or TASS were noted. **Conclusion:** Thus, Intracameral injection of mydriatic provides rapid and sustainable mydriasis and analgesia for manual SICS.

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Cataract is the most prevalent cause of blindness, accounting for 62% of the total prevalence of blindness.<sup>[1,2]</sup> Modern cataract surgery aims to achieve a better unaided visual acuity with rapid post-surgery recovery and minimal surgery-related complications. Small-incision cataract surgery provides rapid, safe, and reproducible results in terms of visual rehabilitation.

Most cataract surgeries can be performed under local anesthesia, which can be either topical or orbital regional anesthesia.<sup>[3]</sup> Topical route has been shown to be a safe and effective alternative to retrobulbar and peribulbar anesthesia.<sup>[4]</sup> Lignocaine was discovered in 1946 and can be given through intravenous, subcutaneous, topical, intracameral, and oral routes. The three most common approaches in providing regional anesthesia via nerve blocks are the retrobulbar block, peribulbar block, and the sub-Tenon block. The major benefit of the retrobulbar block is the deposition of the local anesthetic in the intraconal portion of the eye, which will provide maximum akinesia to the extraocular muscles with a success rate of approximately 85%.<sup>[5,6]</sup>

The peribulbar block can be performed with a 25- to 27-gauge needle. It is a safer alternative than the retrobulbar block and is becoming more popular when providing anesthetic care.<sup>[7]</sup> Peribulbar injection of lignocaine hydrochloride has been the method of choice for preoperative anesthesia and analgesia till date.<sup>[8]</sup> But procedure-related complications like

pain, perforation of globe, retinal detachment or vitreous hemorrhage have been reported. It can also rarely cause retinal vascular occlusion, retrobulbar hemorrhage, strabismus, ptosis, optic nerve damage, and even cardiac or respiratory arrest.<sup>[7]</sup>

Nowadays, the patient prefers injectionless surgery so topical or intracameral anesthesia can be considered. It saves time and resources, especially in centers with high volume of surgeries. Intracameral (IC) administration of mydriatics is an alternative to the traditional topical regimen for cataract surgery. Three randomized clinical trials<sup>[9–11]</sup> reported that the adjunct of intracameral lidocaine 1% decreases pain at various points during the surgery and after the surgery compared with groups receiving topical anesthesia and placebo intracamerally. Topical regimen for preoperative mydriasis is time-consuming. Poor bioavailability of topical drug leads to delay in onset of mydriasis. It can also cause ocular surface toxicity and cardiovascular side effects in some cases. Thus, a combination of intracameral lignocaine hydrochloride and tropicamide can be considered as an alternative for cataract surgery.

Along with anesthesia, adequate intraoperative pupillary dilatation and sustained mydriasis is required for good surgical outcome in cataract surgery.

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## Methods

After receiving clearance from the institutional ethical board, this prospective, observational study was initiated. The study was conducted from October 2021 to March 2022 for 6 months duration.

Commercially available injection (inj.) phenocaine plus 1 ml, a combination of phenyl epinephrine (0.31%), tropicamide (0.02%), and lidocaine (1%) was used. An advantage of IC mydriatics or anesthetics is the substantially increased bioavailability resulting in decreased systemic absorption.

It is a single-dose therapy given via the intracameral route in manual small-incision cataract surgery (MSICS) prior to capsulorhexis.

All cases underwent SICS by a single surgeon. Standard operative sterilization protocol was observed and the surgical steps were done using Zeiss Lumera 300 microscope. After performing peritomy, bleeders were cauterized, scleral incision was fashioned, and through side port incision intracameral inj. phenocaine plus 1 ml was injected in the anterior chamber (AC). Capsulorhexis was created with a 26-Gauge bent cystotome. The nucleus was prolapsed in the AC and delivered with the help of Vectis. Cortical cleanup was done with a Simcoe canula. Standard polymethylmethacrylate (PMMA) single piece IOL was inserted in the bag. Pupil size was measured at various stages of surgery.

### Assessment of mydriasis

Pupillary dilatation was noted in millimeters. The 6-mm cutoff value was adopted because the Lens Opacities Classification System III (LOCS III) scale, which is used to assess cataract maturity, requires that the pupils are dilated to a diameter of  $\geq 6$  mm. If the mydriasis was inadequate intraoperatively, the surgeon decided either to reinject intracameral mydriatic solution or to apply other methods of pupil dilation whenever required.

Pupillary dilatation was measured on screen captures taken at five specific stages during surgery: preoperative (T1), 20 seconds after injecting phenocaine plus injection (T2), before capsulorhexis (T3), after cortical wash (T4), after IOL insertion (T5).

The exact pupil size during surgery was obtained using the following formula:

Pupil size = pupil size on photograph (screen capture)  $\times$  corrective factor.

Corrective factor = real HVID/HVID on photograph.

### Pain assessment

Patients were specifically asked about sensation of pressure and pain in the eye or orbit using a six-point ordinal scale during surgery.

0 = no pain or pressure;

1 = mild sensation of pressure but no discomfort;

2 = mild discomfort due to sensation of pressure;

3 = mild pain;

4 = moderate pain;

5 = severe pain.

### Postoperative assessment

Unaided Snellen visual acuity was evaluated on first postoperative day.

All the patients were graded for corneal edema from 0 to 3 as none, mild (Descemet folds only), moderate (stromal edema with Descemet folds), and severe (stromal and epithelial edema).

AC inflammation was evaluated by estimating the number of cells in a 1 mm by 1 mm slit beam field and was graded from 0 to 4 as 0 (no cells seen), 0.5 (1–5 cells), 1 (6–15 cells), 2 (16–25 cells), 3 (26–50 cells), and 4 (>50 cells).

## Results

The collected data were analyzed with descriptive statistical methods by using Microsoft Excel 2016. Data was expressed as the mean and standard deviation, median with ranges, or percentage where appropriate.

Out of 32 cases in the study, 19 (59.3%) were male and 13 (40.7%) were females. The median age of the study sample was 65 years (range 43–78 years).

Table 1 shows the demographic profile and laterality of cases included in the study.

Fig. 1 (Pie chart) shows distribution of cases according to cataract grading.

An increase of  $0.7 \pm 0.283$  mm from baseline pupillary diameter of  $3.45 \pm 0.40$  mm was noted. The peak value of  $7.49 \pm 0.27$  mm was attained following intracameral injection of a mydriatic solution which was sufficient to make an adequatesized capsulorhexis and nucleus delivery into the AC.

Dilatation gradually reduced to  $7.11 \pm 0.44$  mm after cortical wash due iris touch and  $6.37 \pm 0.52$  mm just before IOL implantation to reach  $5.29 \pm 0.51$  mm by the end of the surgery.

Fig. 2 (Line chart) shows pupillary diameter in mm at various stages of surgery.

Fig. 3 show picture depicting surgical stages and corresponding pupillary diameter.

**Table 1: Demography and cataract profile of cases**

|                 |                       |                       |
|-----------------|-----------------------|-----------------------|
| Gender          | Male 19 (59.3%)       | Female 13 (40.7%)     |
| Laterality      | Right Eye -17 (53.1%) | Left Eye - 15 (46.8%) |
| Nucleus Grading | Nucleus Sclerosis:    |                       |
|                 | Grade I - 3 Cases     |                       |
|                 | Grade II - 11 Cases   |                       |
|                 | Grade III - 14 Cases  |                       |
|                 | Grade IV - 4 Cases    |                       |

**Table 2: Postoperative status**

| Parameters              | Postoperative Day 1 (n=32)   |
|-------------------------|--|
| Visual Acuity (Unaided) | 6/18-6/12 Mean is 6/15   |
| Corneal Edema           | None - 14 cases<br>Mild - 17 cases<br>Moderate - 1 (Resolved in one week)<br>Severe - 0        |
| AC Reaction             | Grade 0-9 cases<br>Grade 0.5-16 cases<br>Grade 1-7 cases<br>Grade 2-0 cases<br>Grade 3-0 cases |

Table 2 shows post-operative parameters like VA, Corneal Status and AC reaction.

Fig. 4 (Pie chart) shows distribution of cases according to AC reaction.

During surgery, most of the patients remained comfortable and only 12 cases (37.5%) reported mild pain of grade 1 on the ordinal scale. We noticed decreased patient's perception of intraoperative pain and increased cooperation with intracameral use of phenocaine plus injection.

### Discussion

Adequate pupillary dilatation and maintenance of mydriasis is very important for an uncomplicated cataract surgery.<sup>[12]</sup> Currently, the most prevalent method for achieving mydriasis for surgery is repeated administration of mydriatic and NSAID eye drops topically preoperatively. But it requires additional manpower and human error can lead to inadequate dilatation

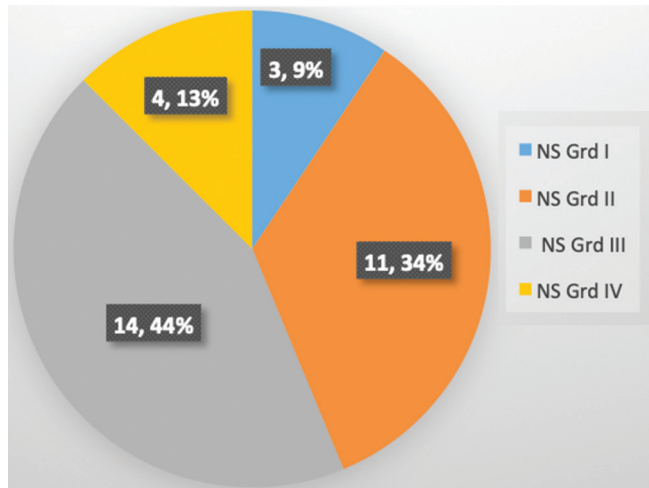


Figure 1: Distribution of cases according to grade of cataract

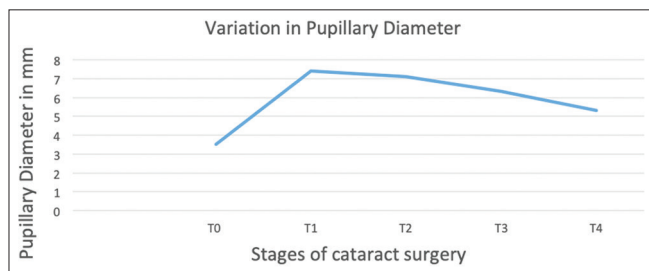


Figure 2: Pupillary diameter in mm at various stages of surgery. T0: Preoperative pupil diameter, T1: 20 seconds after intracameral injection, T2: After cortical wash, T3: Before IOL insertion, T4: At the end of the surgery

or dilatation of the wrong eye. To obviate these disadvantages, intraoperative intracameral mydriatic solutions were introduced. Many authors have reported such solutions to be effective and safe.<sup>[13-17]</sup> Crandall *et al.*<sup>[9]</sup> in 1999 and Ajay *et al.*<sup>[8]</sup> in 2017 concluded that use of IC anesthetic increased patient's comfort, especially during IOL implantation and led to greater surgeon's satisfaction. Epinephrine is a known risk factor for pseudophakic cystoid macular oedema, but intracameral epinephrine at a concentration of 0.2 mg/mL or lesser (1:5000) has been shown as not to be associated with increased risk of central macular oedema.<sup>[18]</sup>

Donnenfeld *et al.*<sup>[19]</sup> conducted a study that focused not only on pupil dilators but also on anti-inflammatory agents and means of maintaining mydriasis with medications injected intracamerally. Study done by Eggeling *et al.*<sup>[10]</sup> showed that 1% intracameral lignocaine was safe for corneal endothelium, but its toxicity was related to the concentration. Eggeling *et al.*<sup>[10]</sup> concluded that low concentration of 1% lidocaine did not cause endothelial cell toxicity and recommended the use of a lower concentration of lignocaine and epinephrine. It can enhance the safety by reducing the toxicity to intraocular structures apart from retaining all the advantages offered by intracameral mydriatic solution.

In our study, the pupillary dilatation achieved by the use of intracameral mydriatic solution was adequate for the entire surgical procedure which took 14 minutes on average (range: 9–16 min with SD ± 1.6). There was a weak positive correlation between the pupil size and the duration of the surgery, which was statistically insignificant (Spearman correlation coefficient 0.13, *P* = 0.46).

In our series we reported reduction in pupillary diameter from 7.35 mm to 5.29 mm at the end of the surgery. Ajay *et al.*<sup>[8]</sup> reported similar pattern of dilation in MSICS with intracameral mydriatics in the study done in 2017. This was in contrast to the study by Gupta *et al.*<sup>[13]</sup> who reported an average intracameral dilation size of 6.9 mm increasing to 7.0 mm at the end of surgery, in patients undergoing phacoemulsification cataract surgery. Two of our cases required reinjection. We believe that the increased intraoperative iris manipulations during MSICS contributed to this decrease in size of pupil unlike in phacoemulsification. Lundberg *et al.*<sup>[14]</sup> also reported constriction of pupil in topical group, in their trial on intracameral versus topical mydriatics for phacoemulsification surgery.

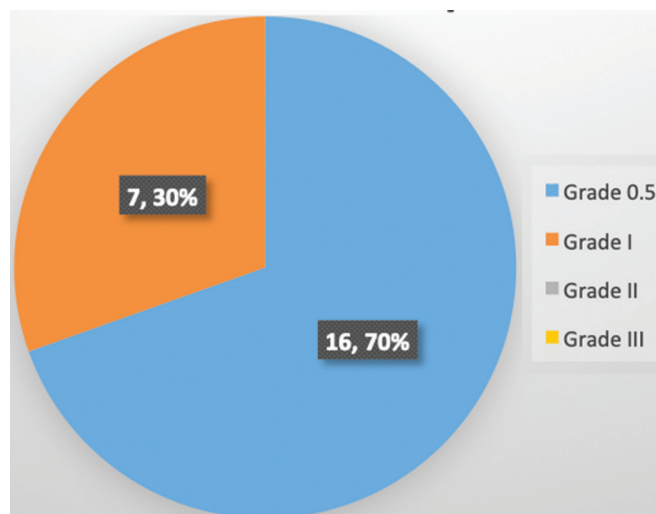
We reported no significant corneal edema or anterior chamber reaction in the postoperative period in our study subjects and this was observed in other studies as well.<sup>[8,13]</sup>

### Conclusion

Intracameral mydriatic injection is found to be effective with regard to dilatation, rapidity, patient comfort, and compliance



Figure 3: Various stages of pupillary dilatation. (a) Predilatation (b) 10 Sec post injection, (c) Intraoperative 7.5mm, (d) Post cortical wash, (e) Post IOL insertion



**Figure 4:** Distribution of cases according to AC reaction

and the main benefit being reduction in nursing time to administer drops.

#### Limitations

The sample size was small and a study with a larger sample would be ideal.

#### Financial support and sponsorship

Nil.

#### Conflicts of interest

There are no conflicts of interest.

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