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# A intracameral combination of tropicamide, phenylephrine and lidocaine in phacoemulsification

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**Background:** Although the benefits of intracameral mydriatics have been established in healthy patients, their safety and efficacy in difficult subjects have yet to be determined.

**Aim:** The aim of the study is to assess the safety and efficacy of topical and intracameral application of a combination of tropicamide, phenylephrine and lidocaine during phacoemulsification surgery.

**Setting:** The study was done at the Department of ophthalmology at the University of Bhavnagar, Gujarat, India.

**Methods:** A total of 50 patients were recruited patients who were operated with phacoemulsification surgery. During the intraoperative period, pupil seize was studied and eventual adverse events have been monitored. Also, comfort reported by patients and surgeons has been investigated.

**Results:** It was observed that the intracameral drug combination did not have any impact on blood pressure, pulse rate as well as did not affect the Intra Ocular Pressure (IOP) dynamics and was successful in maintaining pupil size after its application during surgery.

**Conclusion:** The combination also proved effective as an anaesthetic agent, which was proven by pain score findings, as the patients were comfortable and compliant enough to tolerate cataract surgery.

**Contribution:** The mydriatic and anaesthetic combination is efficient enough used topically and intracamerally to carry out phacoemulsification surgery and has a better safety profile when compared with current practices.

**Keywords:** intracameral application; phacoemulsification surgery; cataract surgery; pupil size; Mydrane.

## Introduction

Cataract being one of the most common causes of the treatable blindness in the country, overall prevalence of blindness being 1.1%, among which the principal cause being cataract (62.6%) affecting over 9 million people.[1] According to an estimation based on a national survey, the number of surgeries required to clear backlog of severe visual impairment because of cataract is 4.9 m.[2] As we take into account cataract's prevalence and the progressive rise in incidence that has coincided with the ageing of the Indian population, cataract currently has a substantial socio-economic impact. As a result, a cataract operation must be optimised to have a smaller financial impact on healthcare.[3]

In the current scenario, the mode of pupil dilatation is by topical application of mydriatic drops that have a potential side effect on the ocular surface, systemic side effects and many a time unable to maintain a sustained pupillary dilatation throughout the cataract surgery; also the current modality in achieving anaesthesia for cataract surgery is by peri bulbar block that has side effects of its own as well as potential disadvantages.

The micro-incisional phacoemulsification surgery along with intracameral phenylephrine (0.31%), tropicamide (0.02%) and lidocaine (1%) enabled for shorter hospital stays, faster recovery times after surgery and reduced preoperative preparation time.[4]

Significant advantages of intracameral mydriatics over topical therapy (which frequently requires multiple administrations to achieve adequate effects and medication-related errors as well as some amount of systemic side effects have already been established). These advantages include

single-use, limited ocular surface toxicity and a decreased incidence of cardiovascular and other systemic side effects.[5]

Thus, this prospective analysis was carried out to observe the effectiveness and safety of intracameral phenylephrine (0.31%), tropicamide (0.02%) and lidocaine (1%) (Mydrane) in patients undergoing phacoemulsification cataract surgery.

## Material and methods

This study was conducted from July 2021 to November 2022 at our tertiary hospital. All procedures in this study concerning its conduction and documentation were performed in conformity with the ethical principles set out in the Helsinki Declaration and its revisions. The intracameral mydriatic featured a salt-balanced and pH-balanced solution composed by two mydriatics (tropicamide 0.02% and phenylephrine 0.31%) and one anaesthetic agent (lidocaine 1%). The patients recruited were enrolled for phacoemulsification surgery with Intra Ocular Lens (IOL) implantation and were aged between 45 and 75 years At the baseline visit, the dilated pupil diameter of at least 6 mm had to be obtained 30 min after the instillation of phenylephrine 5% and tropicamide 0.8% eye drops. At this selection visit, patient's data were gathered, including past medical and ophthalmological history. The exclusion criteria were: mydriasis < 6 mm, history of ocular trauma and congenital cataract. Informed consent has been obtained in written form for all participants. This study received the approval from the Institutional Ethics Committee. The selected patients underwent cataract surgery with phacoemulsification technique and IOL implantation. Furthermore, individuals who need an extra intra-operative use of mydriatic, presenting intraoperative complications related to the surgical procedure have been identified (Figure 1). A single surgeon with the same technique performed all surgical procedures. The same surgeon with a Castroviejo calliper measured pupil diameter in several specific stages of the procedure: preoperatively (T1), just before corneal incision (T2), 30 s after injection of drug (T3), just before capsulorhexis (T4), just before IOL insertion (T5) and end of surgery (T6).

Follow-up examinations were scheduled on day 1 and 1 week postoperatively. The primary efficacy outcome was the achievement of an acceptable mydriasis (pupil diameter of at least 6 mm) [4–6] just before capsulorhexis. Secondary outcomes was to observe any adverse effect on blood pressure, pulse, significant ECG changes main postoperative outcomes included: Intraocular pressure dynamics, anterior chamber reactivity, central corneal thickness, central macular thickness observation for possible local and systemic adverse events has been performed in the groups under study, during each follow-up visits. Furthermore, for each procedure, patient comfort and surgeon satisfaction have been reported.

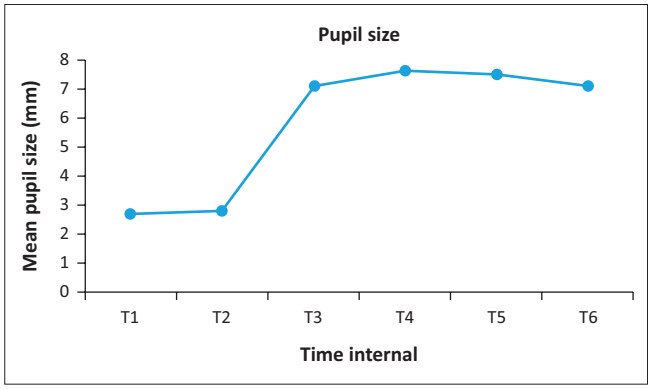


**FIGURE 1:** Mean pupil diameter at various time interval during the surgery.

### Statistical analysis

Statistical significance of differences between groups was calculated with Student's t-test for non-parametric variables. Descriptive statistics were calculated for quantitative variables using the test F based on Fisher-Snedecor distribution. Differences between groups were tested with a two-sided 95% confidence interval (CI). Repeated intervals data measured by repeated measured ANOVA method. Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) Windows version 26.0 (SPSS Inc., Chicago, IL, United States) and Microsoft Excel.

### Ethical considerations

Ethical clearance to conduct this study was obtained from the Government Medical College Ethics Committee (No. 1035/2021).

## Results

A total of 50 patients were enrolled who underwent phacoemulsification surgery at our tertiary care centre. Overall, the mean age of study was 62.42 ± 6.83 years. Among total study population, 56% were males, whereas 44% were females. The age group of 66 year olds – 70 year olds was more prevalent in our study, whereas 45 year olds – 50 year olds age group was least common. The primary outcome was to observe the pupil size during the cataract surgery after giving the recommended dose of the drug.

It was observed that 2.7 ± 0.51 mm was the mean pupil diameter before surgery and after 30s of injecting the drug and before IOL insertion, observed mean pupil diameter was 7.07 ± 0.9 mm and 7.45 ± 1.23 mm, respectively, thus allowing easy manoeuvre of the intraocular lens. These changes in mean pupil diameter were statistically significant (Huynh Feldt).($P \leq 0.0001$) (Figure 1).

The given figure shows significantly increasing mean pupillary diameter in (mm) after injecting the drug and mean pupillary diameter in (mm) being maintained effectively throughout the crucial steps of surgery.

There was no significant difference between pre-operative and postoperative pulse rate ($P = 0.7958$), systolic blood pressure (SBP) ($P = 0.053$) and diastolic blood pressure (DBP) ($P = 0.2750$). Thus, intracameral administration of tropicamide

(0.02%), phenylephrine (0.3%) and lidocaine (1%) combination did not affect the pulse rate, SBP and DBP.

The pain score was assessed by visual analogue scale showed to the patient after surgery. Seventy-two per cent of the patients felt milder form of tolerable pain in patients with combination drug (Figure 2). It was noted that the mean intraocular pressure prior to surgery was 16.86 mmHg ± 1.34 mmHg, whereas on follow-up at 1st and 3rd day, postoperative intraocular pressure was 16.42 mmHg ± 1.13 mmHg and 14.4 mmHg ± 0.67 mmHg, respectively. These changes in intraocular pressure were statistically significant (Greenhouse Geisser) ($P \leq 0.0001$). According to our observation, intraocular pressure was within normal limit, and no adverse effect of our combination drug was observed on the Intra Ocular Pressure (IOP) dynamics (Table 1).

There was no clinically significant difference between preoperative and 7th day of postoperative central corneal thickness ($P = 0.1629$). Additionally, it was noted that CCT increased following surgery on the first postoperative day and dropped on the 7th postoperative day. In addition, there was no any significant evidence of corneal oedema or Descemet membrane detachment on anterior segment Optical Coherence Tomography (OCT).

There was no significant difference between preoperative and 7th day of postoperative central macula thickness ($P = 0.1969$). There was no any significant change in macular oedema any pathology of macula.

The findings of inflammation were observed by observing the cells in the anterior chamber using the Standardisation of Uveitis Nomenclature (SUN) classification, and there was milder form of iritis observed on day 1, which subsided by day 3 in the majority of patients (Figure 3; Table 2).

Majority of the patients had sufficient pupillary dilatation and optimum anaesthesia, which excluded the need for additional drug doses while only a small proportion of the patients (6%) required a second dose of 0.2 cc intracamerally, which was sufficient enough to complete the cataract surgery (Figure 4; Table 3).

It was observed that out of all 50 patients undergoing cataract surgery, 2 patients were reported to have inadvertent posterior capsular rent, which was successfully managed

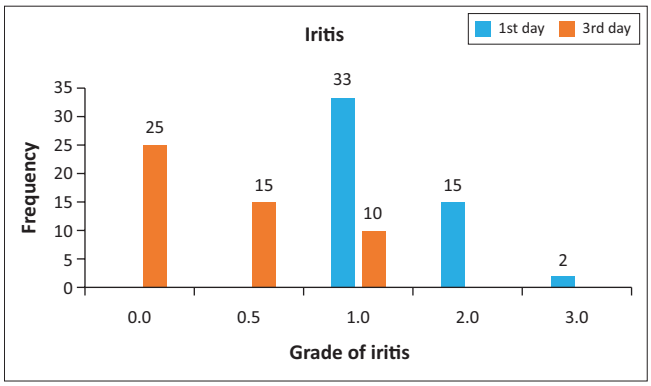


**FIGURE 3:** Inflammation being subsided on the 3rd post-operative day.

**TABLE 2:** Showing findings of inflammation as graded on SUN classification on respective time.

| Grade of iritis observed by SUN classification | 1st day | | 3rd day | |
|---|---|---|---|---|
| | *n* | % | *n* | % |
| 0.0 | - | - | 25 | 50 |
| 0.5 | - | - | 15 | 30 |
| 1.0 | 33 | 66 | 10 | 20 |
| 2.0 | 15 | 30 | - | - |
| 3.0 | 2 | 4 | - | - |

SUN, Standardisation of Uveitis Nomenclature.

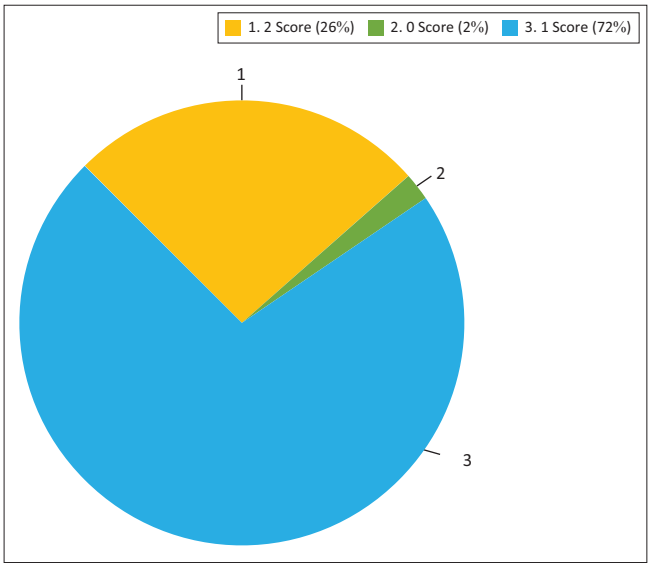


**FIGURE 2:** Percentage of patients and corresponding pain score.

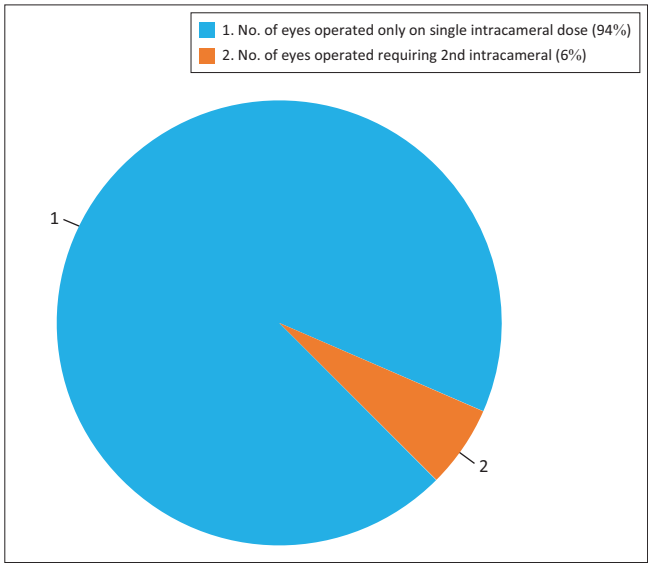


**FIGURE 4:** Dosing frequency of drug.

**TABLE 1:** Showing mean intra ocular pressure measured at respective time intervals.

| Variables | Pre-operative | 1st Day postoperative | 3rd Day postoperative | Mauchy's *W* | Greenhouse geisser | *P* |
|---|---|---|---|---|---|---|
| IOP | 16.86 ± 1.34 | 16.42 ± 1.13 | 14.4 ± 0.67 | 0.733 | 0.789 | < 0.0001 |

IOP, intra ocular pressure.

**TABLE 3:** Dosing frequency of the drug.

| Variables | No. of eyes operated only on single intracameral dose | No. of eyes operated requiring 2nd intracameral | No. of eyes operated requiring 3 or more intracameral dose | No. of eyes operated requiring other forms of mydriatic or anaesthetic |
|---|---|---|---|---|
| No. of patients | 47 | 3 | 0 | 0 |
| Percentage | 94 | 6 | - | - |

No., number.

**TABLE 4:** Complications of cataract surgery.

| Variables | Patients who had uneventful cataract surgery | Patients undergoing inadvertent event during cataract surgery |
|---|---|---|
| No. of patients | 48 | 2 |
| Percentage | 96 | 4 |

No., number.

on this Mydrane combination with anterior vitrectomy performed with PMMA lens placed in sulcus with corneal suture taken (Table 4).

# Discussion

Obtaining adequate, quick and stable mydriasis is one of the key points of every cataract surgery. Mydriatic eye drops are currently the standard method for pupil dilation in cataract surgery, but their limitations such as repeated instillation, systemic side effects, ocular surface toxicity also limitation of peribulbar block for ocular anaesthesia such as invasiveness, raised IOP, globe injury, chemosis and oculocardiac reflex have provoked a search for different techniques.[4]

Combination of tropicamide (0.02%), phenylephrine (0.3%) and lidocaine (1%) is standardised mixture of mydriatics and anaesthetic for injection in the anterior chamber designed for an effective cataract surgery. The active components, concentrations and volumes in the Mydrane formulation were based on the efficacy and safety of other IC formulations used for phacoemulsification cataract surgery.[5,6,]

A previous randomised clinical trial demonstrated that intracameral administration of Mydrane just after the first injection intracameral produces rapid and adequate mydriasis in non-complicated patients, allowing phacoemulsification in regular conditions, showing similar efficacy with the standard topical regimen.[3] The active components, concentrations and volumes in the final formulation were based on the efficacy and safety of other intracameral formulations used for phacoemulsification in cataract surgery.[5,6]

Intracameral administration of tropicamide (0.02%), phenylephrine (0.3%) and lidocaine (1%) can provide a considerable reduction in preoperative preparation time as required in case of topical mydriatics requiring repeated instillation with significant mydriasis, anaesthesia. Preoperative time was much lower in the intracameral mydriatic group as there was no requirement for topical drops preoperatively. A reduction in time spent in the preoperative room can also lead to a less stressful experience for patients also the toxic effects of the topical drops on the ocular surface as well as systemic side effects can be eliminated and a good surgical outcome can be ensured.

Therefore, this study was undertaken to evaluate the efficacy and safety of topical and intracameral application of combination of tropicamide (0.02%), phenylephrine (0.3%) and lidocaine (1%) applied during phacoemulsification surgery.

## Overall mean age of study

Overall, the mean age of our study population was 62.42 ± 6.83. The mean age of study having similar findings in a study by Gupta et al.[7] and Nuzzi et al.[8] was 64.3 ± 8.8 and 66 ± 12.52, respectively.

## Pupil size

After intracameral administration of tropicamide (0.02%), phenylephrine (0.3%) and lidocaine (1%) the increase in mean pupil size was up to 4.33 in our study. Our study is comparable to Nikeghbali et al.[9] study. In his study, the overall mean difference in pupil size was 4.58 after intracameral application.

Our study is also consistent with the findings of Gupta et al.[7]. In his study, the overall mean difference in pupil size was 4.8 after intracameral application. So, we could say that after intracameral administration of tropicamide (0.02%), phenylephrine (0.3%) and lidocaine (1%) there was an increase in mean pupil size up to 4 mm.

Our study reveals that mean pupil size was 6.94 ± 0.89 observed after injection of viscoelastic injection, whereas 7.45 ± 0.21 was observed after IOL implantation. These findings were similar to that of Tseng et al., 1998.[10]

## Pulse

In the study, it was observed that the mean pulse rate was 76.92 ± 9.06 beats per minute at baseline at the end of surgery. This overall mean change between pre and post pulse rate was non-significant. Our findings were consistent with those of a related study conducted by Lundenberg et al.[5], which found no discernible difference in pulse rate between pre and post intervention.

## Blood pressure

The overall mean change in SBP ($P$ = 0.053) and DBP ($P$ = 0.2740) was 1.58 and 0.98, respectively, with an insignificant difference when comparing pre-operative to post operative SBP. Our study was comparable to another similar study with Bekir et al.[11]

## Central corneal thickness (our combination drug vs. eye drop)

It was observed that 14.12 $\mu$m rise in CCT on 1st post operative day which decreased to subclinical preoperative value on 7th day during follow-up in our study ($P$ = 0.0131),

whereas Chaudhry et al.[12] who had performed the study on patients undergoing phacoemulsification by topical mydriatic drops ($P \leq 0.0001$) also observed 23.01 $\mu$m rise in CCT after phacoemulsification surgery on the 1st postoperative day.

### Central macular thickness

It was observed that 12.92 $\mu$m was rise in Central Macular Thickness (CMT) on the first postoperative day, whereas Lohani et al.[13] who had performed the study on patients undergoing phacoemulsification by topical mydriatic drops also observed 10.74 $\mu$m rise in CMT after phacoemulsification surgery on the 1st postoperative day.

### Pain score

A total of 2% patients reported no pain (a score of 0), 72% had minimal discomfort (a score of 1) and none of the patients reported a pain score of 3 or above (Figure 1). The mean pain score of our study population was 0.47 ± 1.24, and our study was comparable with Tseng et al.,[10] wherein mean pain score was 0.37 ± 0.58.

### Intra ocular pressure

According to our study, we observed intraocular pressure having 16.86 ± 1.34 at baseline, and at the end of follow-up, we observed 14.4 ± 0.67 intraocular pressure during our observation. Our study was comparable to another similar study by Behndig et al.[14] They observed 15.6 ± 2.7 intraocular pressure after surgery showing no any adverse effect on the IOP dynamics.

### Iritis

The findings of inflammation were observed by noting the iritis using the SUN classification and milder form of iritis was observed on day 1, which subsided by day 3 in the majority of patients.

## Conclusion

The pain score results demonstrated the effectiveness of the intracameral medication combination as an anesthetic, as the patients were able to tolerate cataract surgery with sufficient comfort and compliance. It does not have any adverse effect on SBP, DBP and pulse rate in patients suggesting the combination devoid of potential systemic side effects. It was observed that intraocular pressure was within the normal range after surgery with no significant rise in the intraocular pressure, which suggested that the IOP dynamics was not altered because of combination and there was sufficient pupillary dilatation achieved by intracameral application of the drug that was maintained throughout the surgery in majority of cases.

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### Competing interests

The authors declare that they have no financial or personal relationships that may have inappropriately influenced them in writing this article.

### Authors' contributions

D.N., H.T & R.P., all contributed equally to this article.

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### Data availability

The data that support the findings of this study are available from the corresponding author, D.N., upon reasonable request.

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