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Dr. Manjula S
Sr. Vice President, Department
of Medical Services, Micro Labs
Limited, Bangalore,
Karnataka, India

Krishna Kumar M
Department of Medical
Services, Micro Labs Limited,
Bangalore, Karnataka, India

Corresponding Author:
Dr. Manjula S
Sr. Vice President, Department
of Medical Services, Micro Labs
Limited, Bangalore,
Karnataka, India

Expert opinion on the use of tropicamide + phenylephrine + lidocaine combination for the appropriative pupil dilation during cataract surgery

Manjula S and Krishna Kumar M

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Abstract

Objective: To collect expert opinion regarding the prescription pattern and clinical use of intracameral medication tropicamide + phenylephrine + lidocaine during cataract surgery in Indian settings.

Methodology: This cross-sectional study used a 33-item, multiple-choice questionnaire to collect opinions from cataract surgery specialists. The survey covered topics such as current clinical observations, patient preferences, experiences with cataract surgery, and the usage of tropicamide + phenylephrine + lidocaine in combination for the appropriate pupil dilation during cataract surgery. Descriptive statistics were applied to the data analysis.

Results: Among the 212 clinicians surveyed, 44% had 6-15 years of experience in clinical ophthalmology, with about 50% specializing in cataract surgery. Despite the use of preoperative mydriatics, <10% of patients had small pupils (< 5 mm) at the beginning of surgery. The combination of tropicamide + phenylephrine + lidocaine injection was highly favored, with 67% noting no significant learning curve. Approximately 74% of the experts reported that the use of intracameral medication was the fastest technique with minimal impact on surgery time. The combination was considered highly effective by 40% of clinicians, and 50% reported achievement of full pupil dilation in 6-10 seconds. As reported by 41% of the experts, postoperative issues such as pain and discomfort were noted only in 1 out of 5 patients and 74% observed minimal postoperative iritis.

Conclusion: The survey has corroborated the safety and efficacy of combination of tropicamide + phenylephrine + lidocaine injection for achieving optimal pupillary dilation in cataract surgery. Most clinicians reported minimal adverse effects with the combination, with the attainment of rapid and sustained mydriasis.

Keywords: Cataract surgery, pupil dilation, tropicamide, phenylephrine, lidocaine

Introduction

Cataract is the leading cause of visual impairment and blindness worldwide. Approximately 17.7 million cases of blindness are attributed to cataract, accounting for 47.8% of all blindness cases ^[1]. The prevalence of cataract and the disability-adjusted life years (DALYs) associated with the condition peaked in 2000 and 2017, with rates of 94.52 and 1283.53 per 100,000 populations respectively ^[2]. In India, cataract was responsible for 80% of blindness cases. However, very few population-based studies have investigated the risk factors for cataract in older age groups, partly due to the notable increase in the elderly population ^[3].

With more than 20 million procedures done annually, cataract surgery is the most common elective procedure performed globally. The expected range of annual cataract surgery rates in economically developed nations was between 4,000 and 10,000 procedures per million individuals ^[4]. To induce mydriasis for eye examination, sympathomimetics like phenylephrine hydrochloride and sympatholytic medications like tropicamide were frequently used, either separately or in combination and in varying doses ^[5]. This helps to minimize intraoperative complications and ensure adequate exposure to the cataract during surgery.

Tropicamide was considered as relatively safe medication to induce mydriasis ^[6]. It was a muscarinic antagonist and anticholinergic agent that induces mydriasis and cycloplegia by blocking muscarinic receptors in the eye, thereby inhibiting the normal parasympathetic control of the pupillary sphincter and ciliary muscles ^[6].

Direct-acting sympathomimetic amine phenylephrine hydrochloride induces mydriasis by activating alpha-1 adrenergic receptors located on the smooth muscle cells of blood vessels and the iris dilator muscle. Lidocaine, also known as lignocaine, is a local anaesthetic that works by blocking sodium ion channels on the inside of nerve cell membranes [7]. For individuals undergoing cataract surgery, the first static-dose mydriatic/anaesthetic combination suitable for intracameral injection was tropicamide 0.02%/phenylephrine 0.31%/lidocaine 1% injectable solution [8]. When administered as a single injection, this intracameral preparation produces rapid and sustained mydriasis, lasting until the end of the surgical procedure [8].

The current survey-based study aims to gather expert opinion on preferences, experiences with cataract surgery, and prescription practices and usage of intracameral combinations, particularly tropicamide + phenylephrine + lidocaine for pupil dilation in Indian settings.

Methodology

A cross sectional, multiple-response questionnaire based survey was carried out among ophthalmologists specialized in treating cataract surgery, and usage of intracameral combination for pupil dilation in the major Indian cities from June 2023 to December 2023.

Questionnaire

The questionnaire booklet titled MICS (Mydriatics in Cataract Surgery) study was sent to the ophthalmologists who were interested to participate. The MICS study questionnaire consisted of 33-item, multiple-choice questionnaire to collect opinions from cataract surgery specialists. The survey covered topics such as current clinical observations, patient preferences, experiences with cataract surgery, and the usage of tropicamide + phenylephrine + lidocaine in combination for the appropriate pupil dilation during cataract surgery. The study

was conducted after getting approval from Bangalore Ethics, an Independent ethics committee which was recognized by the Indian regulatory authority, drug controller general of India.

Participants

An invitation was sent to leading ophthalmologists in managing cataract surgery in the month of March 2023 for participation in this Indian survey. About 212 ophthalmologists from major cities of all Indian states representing the geographical distribution shared their willingness to participate and provide necessary data. They were instructed to complete the survey independently, without consulting other colleagues. Prior to commencing the study, each participant provided written informed consent.

Statistical analysis

Descriptive statistics were employed for data analysis. Percentages were used to represent categorical variables. The frequency of occurrence and the corresponding percentage illustrated the distribution of each variable. Microsoft Excel 2013 (Version 16.0.13901.20200) was utilized to create graphs and pie charts depicting the distribution of the categorical variables.

Results

Among the 212 clinicians surveyed, 44% had 6-15 years of experience in clinical ophthalmology practice. Approximately 50% of these clinicians specialized in cataract surgery and around 58% practiced only in this field. Nearly half (48%) of the clinicians had 6 to 15 years of experience specifically in cataract surgery. Approximately 53% of clinicians mentioned that typical urban group patients regularly visit their clinics. Almost half (49%) of the respondents reported that cataract was more prevalent in urban subjects (Fig. 1).

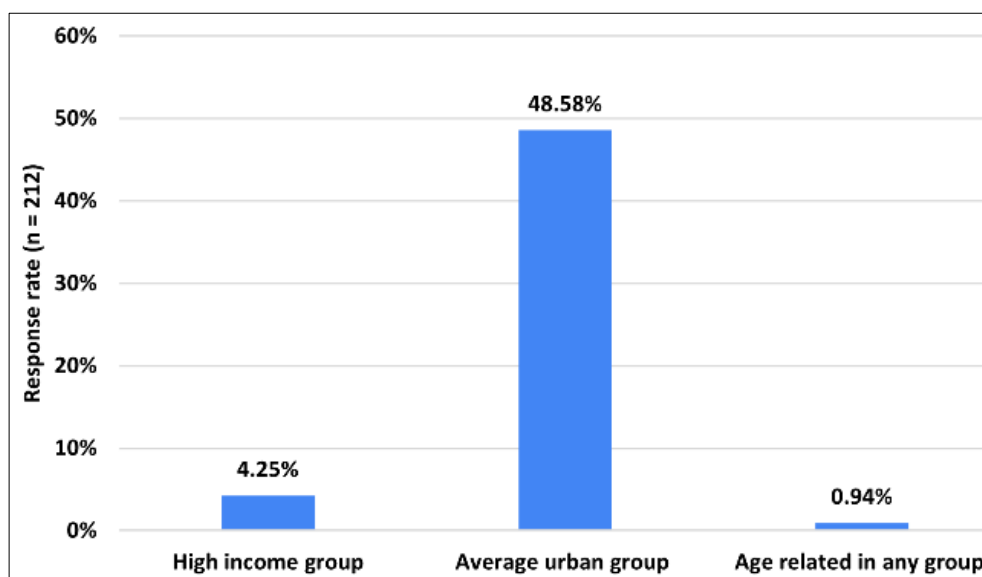


Fig 1: Distribution of response to the severity of cataract in different patient groups presenting to the routine settings

According to 59% of the survey respondents, routine phacoemulsification with monofocal lenses was the most frequently used method for cataract surgery. Approximately 45% of the clinicians noted that on average, urban group patients with cataracts had pupils that did not dilate or were

small. Nearly 30% of respondents pointed out that patients with cataracts and small or no dilating pupils are most frequently associated with pseudo exfoliation. Almost half (48%) of clinicians specified that <10% of their patients had small pupils (<5 mm in size) at the beginning of cataract

surgery despite using preoperative mydriatics. Approximately 44% of participants reported that <5% of patients with well dilated pupils showed constriction to a small pupil (<4 mm) during the cataract surgery with preoperative mydriatics.

Nearly 42% of respondents preferred using Iris hook techniques for managing small pupils. Approximately 67% of respondents stated that there was essentially no learning curve when using intracameral medications as a method for cataract surgery. Majority (74.06%) of the clinicians stated that using intracameral medicines was the fastest technique with little difference in surgery time. According to 89% of

clinicians, a well-dilated pupil was essential for both the best surgical outcomes and the comfort of the surgeon. For patients in whom dilation was intended, 47% of clinicians reported that it typically takes 6-10 seconds to achieve appropriate dilation. According to 42% of respondents, the average time to provide patients with effective ocular anesthesia when the goal was for them to be comfortable was 6–10 seconds. Regarding cataract surgery performed under topical anesthesia, half (50%) of the clinicians recommended the combination of tropicamide + phenylephrine + lidocaine injection as a highly useful choice of medicine (Table 1).

Table 1: Distribution of response regarding the usefulness of the combination of tropicamide + phenylephrine + lidocaine as a standard adjuvant for cataract surgery under topical anesthesia

Usefulness of the combination	Response rate (n = 212)
Not useful	1.42%
Sometimes useful	16.98%
Very useful	50%
Excellent product	31.6%

Approximately 40% of clinicians reported that the combination of tropicamide + phenylephrine + lidocaine injection was highly effective for cataract surgery, considering factors such as convenience of usage, speed of benefit, and cost. According to 50% of physicians, between 30% and 50% of patients were able to fully dilate their pupils (Fig. 2). As reported by 41% of the experts, 1 out of 5 patients experienced pain and discomfort after receiving this combination (Table 2). About 74% of clinicians reported that there was a minimal percentage of patients who developed postoperative iritis (Table 3). Approximately

72% of clinicians reported that 1% to 10% of cases experience unfavorable outcomes, such as toxic anterior segment syndrome, following injectable cataract procedures utilizing tropicamide + phenylephrine + lidocaine. Most of the clinicians (66.51%) stated that a combination medication of 0.2 ml tropicamide + phenylephrine + lidocaine injection was necessary to accomplish pupil dilation (Fig. 3). Approximately 53% suggested that occasionally there was an additional need for mydriatics for successful capsulorhexis.

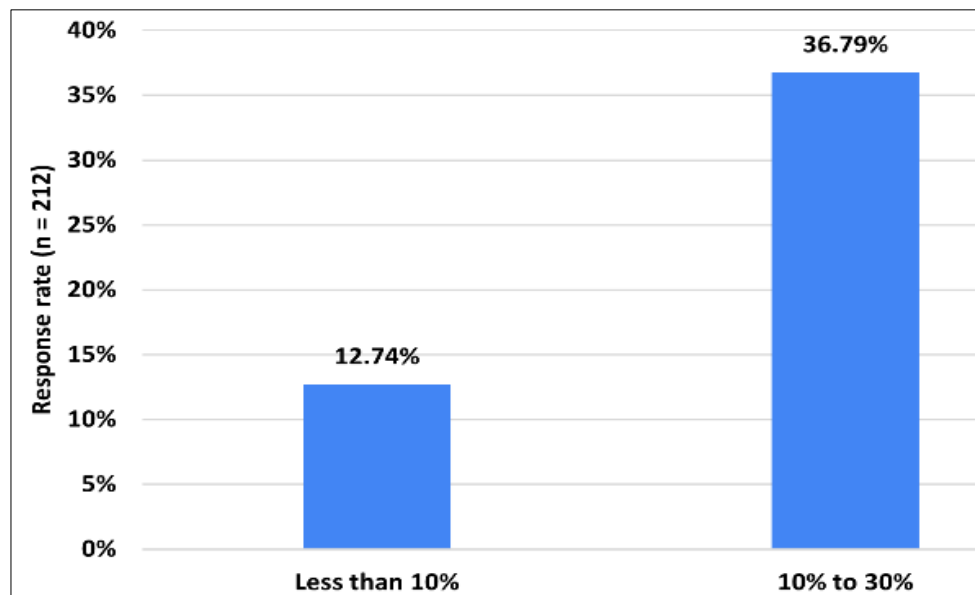


Fig 2: Distribution of response to the proportion of patients with complete dilatation of more than 7 mm in less than 20 seconds after receiving tropicamide, phenylephrine, and lidocaine injection

Table 2: Distribution of response to the number of patients experiencing pain and discomfort after receiving an injection of tropicamide + phenylephrine + lidocaine

Number of patients	Response rate (n = 212)
1	39.15%
2	40.57%
3	12.26%
4	4.72%
5	3.3%

Table 3: Distribution of response to the proportion of patients developing iritis after cataract surgery

Proportion of patients	Response rate (n = 212)
1% to 10%	74.06%
11% to 20%	19.81%
21% to 30%	1.89%
Not encountered	1.42%

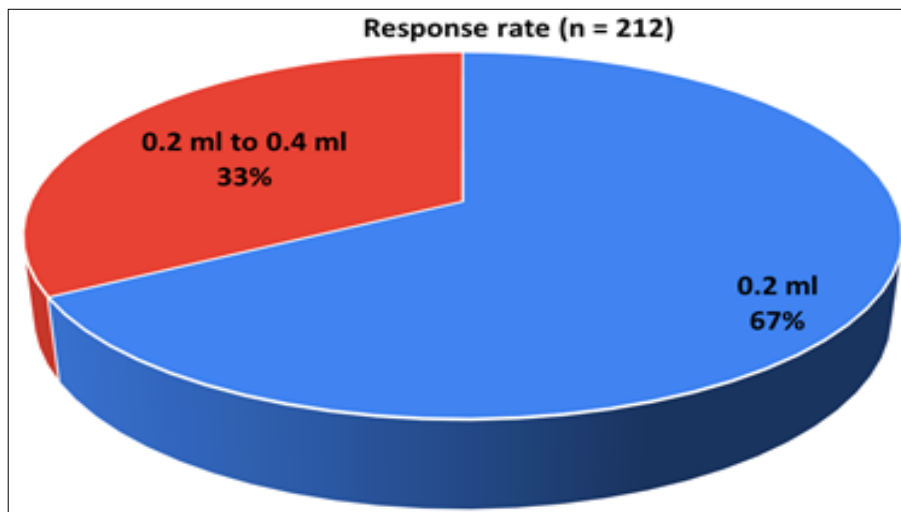


Fig 3: Distribution of responses regarding the volume of intracameral mydriatic required to achieve pupil dilation

According to 59% of the survey respondents, 5% to 10% of patients demonstrated non-inferiority compared to the standard method of using tropicamide and phenylephrine eye drops for dilation, administered three times with a 15-minute interval. About 41% of clinicians stated that the combination of tropicamide + phenylephrine + lidocaine

injection was excellent in maintaining pupillary dilation throughout the operation (Table 4). Around 70% of clinicians suggested that the use of this combination was safe for the corneal endothelium, based on specular microscopy pre- and post-operation (Fig. 4).

Table 4: Distribution of response to the induction of pupillary dilatation following intra-cameral injection and its maintenance during surgery

Maintenance of pupillary dilatation throughout surgery	Response rate (n = 212)
Excellent	40.57%
Good	38.68%
Satisfactory	19.34%
Not good	1.42%

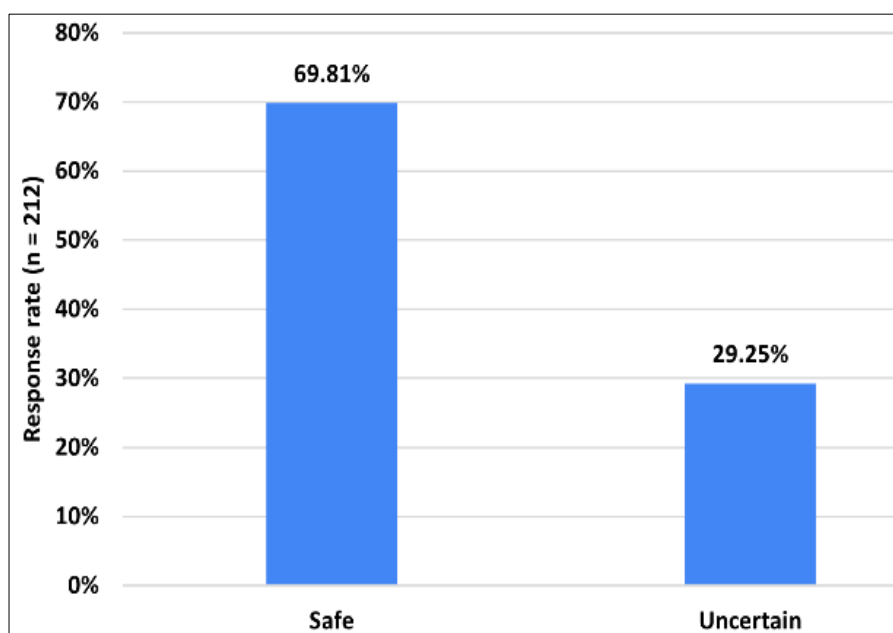


Fig 4: Distribution of response to the safety of tropicamide + phenylephrine + lidocaine injection for the corneal endothelium using specular microscopy before and after surgery

Discussion

The survey-based study provides valuable insights regarding preferences and experiences in cataract surgery and the utilization of intracameral medication, specifically tropicamide + phenylephrine + lidocaine injection, in Indian settings. The survey findings may assist clinicians in making informed decisions to improve patient outcomes.

The current survey underscored the crucial role of a well-dilated pupil in achieving optimal surgical outcomes and ensuring surgeon comfort. Patients with cataracts and small or non-dilating pupils were most frequently associated with pseudo-exfoliation. The survey respondents noted that despite the use of preoperative mydriatics, a small percentage (<10%) of patients still have small pupils (<5 mm in size) at the beginning of cataract surgery. Boris Malyujin stated that a small pupil was a well-known risk factor for various issues both during and after cataract surgery. Inadequate preoperative mydriasis and/or intraoperative miosis can lead to iris trauma and photophobia. The most serious side effects of cataract surgery were anterior capsular tear, increased inflammation, uneven pupil shape, posterior capsular rupture, and retained lens debris. Patients whose pupils do not dilate by a factor of two may experience vitreous loss [9]. Kumari *et al.* emphasized the importance of adequate pupil dilation in cataract surgery. Additionally, adrenaline was often added to the standard topical drops to maintain mydriasis. Similarly, Dereń-Szumelda *et al.* stated that effective mydriasis and anesthesia were fundamental prerequisites for safe and successful cataract surgery, ensuring optimal surgical outcomes and maximum patient comfort [11].

The current survey highlighted that using intracameral medications was the quickest technique, with minimal variance in surgery duration. Similarly, Kumari *et al.* also noted the effectiveness of intracameral mydriatics as an alternative method for pupil dilation. These mydriatics have been proven effective and safe, providing adequate intraoperative mydriasis and analgesia, thus serving as alternatives to standard topical regimens [10]. According to Dereń-Szumelda *et al.*, the standard practice before cataract surgery involves inducing pharmacological mydriasis by applying topical mydriatic eyedrops three times at 5-minute intervals. These drops typically contain 1% tropicamide and/or 10% phenylephrine. Using pupil-dilating drugs with different mechanisms of action facilitates achieving the desired mydriatic effect more efficiently and rapidly [11].

According to the present survey findings, the combination of tropicamide + phenylephrine + lidocaine injection was highly effective for cataract surgery, considering factors such as ease of use, rapid onset of action, and cost-effectiveness. However, there may be occasional need for additional mydriatics to achieve successful capsulorhexis. Majority of the current respondents stated that the average time to achieve effective ocular anesthesia, ensuring patient comfort, ranges between 6 and 10 seconds. A review by Emma D Deeks reported that intracameral tropicamide + phenylephrine + lidocaine enables successful capsulorhexis without the need for additional mydriatics. This intracameral preparation, administered via a single injection, provides rapid and sustained mydriasis throughout the surgery [8].

Majority of the current survey respondents noted that one out of every five patients experienced pain and discomfort after receiving the combination of tropicamide, phenylephrine, and lidocaine. The survey also reported a

minimal occurrence of postoperative iritis following the use of the combination. Similarly, Nayak *et al.* reported that intracameral tropicamide + phenylephrine + lidocaine resulted in a milder form of iritis on day 1, which resolved by day 3 in most patients [12]. According to Aerts *et al.*, intracameral injection with a combination of tropicamide 0.02% + phenylephrine 0.31% + lidocaine 1% was a safe and effective substitute for eye drops in adult patients undergoing cataract surgery have found. This method offers dependable and long-lasting mydriasis, making it a viable option for younger individuals undergoing cataract surgery as well [13].

According to the current survey results, the combination medication of 0.2 ml (About 0.01 oz) of tropicamide, phenylephrine, and lidocaine injection proves highly effective in sustaining pupillary dilation throughout the entire procedure. Furthermore, based on specular microscopy pre- and post-operation, it was considered safe for the corneal endothelium. These findings correspond to those reported by Emma D Deeks. Overall, the combination medicine was reported to be well tolerated, with no serious adverse events leading to hospitalization or permanent vision loss [8].

Combination therapy with tropicamide, phenylephrine, and lidocaine was essential for effective pupil dilation, as agreed upon by many clinicians. The results of the current survey can help physicians improve patient comfort during cataract surgery procedures. The major strengths of the survey were its large sample size and the use of a well-crafted and validated questionnaire to gather data from clinicians. However, it was crucial to recognize the survey's limitations. Since the results rely on expert opinion, which might be influenced by the different perspectives and preferences of clinicians, the risk of opinion-based bias cannot be avoided. When analyzing the results, it was critical to bear this in mind. Further prospective trials and observational studies were warranted to validate the survey results and provide a more thorough understanding of the best practices.

Conclusion

The survey highlighted the importance of a well-dilated pupil for achieving optimal surgical outcomes and ensuring surgeon comfort during cataract surgery. It revealed a strong preference among clinicians for the combination of tropicamide, phenylephrine, and lidocaine injection due to its effectiveness, speed, and safety, thus supporting its use as a standard practice in cataract surgery.

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Conflict of Interest

Nothing to disclose

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