J. Pharm. Res. 2024;23(4):233–236

Print ISSN: 0973-7200
Online ISSN: 2454-8405

Journal of Pharmaceutical Research

RESEARCH ARTICLE

Comparing Topical Mydriatics' Effectiveness in Preserving Pupil Dilation during Small-incision Cataract Surgery

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ARTICLE INFO

Article history:
Received 28.08.2024
Accepted 31.12.2024
Published 31.12.2024

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https://doi.org/10.18579/jopcr/v23.4.83

ABSTRACT

Background: Pupil dilation using topical mydriatics is one of the important pre-requisites prior to performing cataract surgery. There are various mechanisms through which mydriasis can be achieved. Parasympathetic and sympathetic nervous systems control the function of sphincter pupillae and dilator pupillae of the iris respectively. Therefore, parasympatholytic drugs like tropicamide and sympathomimetic drugs like phenylephrine of various strengths are commonly used for the purpose of pupil dilation. **Objective:** The aim of the study was to evaluate the efficacy, sustainability, and safety of topical mydriatics like tropicamide 1%, phenylephrine 10%, both when used alone and in combination of tropicamide 0.8% and phenylephrine 5% eye drops. **Methods:** It is a prospective observational study carried out from January 2024 to June 2024. The study included 87 patients who were posted for manual small incision cataract surgery (MSICS) after considering inclusion and exclusion criteria. **Results:** The patients were randomized into three groups of them receiving topical mydriatics, that is, Group A- tropicamide 1%, Group B- phenylephrine 10% and Group C- combination of tropicamide 0.5% and phenylephrine 5% eye drops. The pupillary diameter was noted at different stages of surgery and the results were analyzed. Following cataract extraction, it was found that the mydriatic effect loss was substantially larger for group A (24.5%) and group B (29%) than for group C (13%). We report the comparison of efficacy of topical mydriatics such as tropicamide 1% and phenylephrine 10% when used alone at a higher concentration, versus their use in combination with reduced strength, that is, tropicamide 0.8% and phenylephrine 5%.

Keywords: Tropicamide; Phenylephrine; Topical mydriatics

INTRODUCTION

Cataract remains one of the leading causes of vision impairment and avoidable blindness worldwide. Among 1 billion people suffering from visual impairment, 94 million were due to cataract.[1] Hence, it becomes imperative to reduce the burden of living and provide timely treatment for the same. Surgical management is the management of choice in treating cataract. Manual small incision cataract surgery (MSICS) is especially prevalent in developing countries like India.[2–4] MSICS is likely the most often used method in high-volume, community-based surgical initiatives, sometimes known as camp operations.[5–7]

The normal pupil size is 2-4mm.[8] Adequate pupil dilatation (approximately 7-8mm) is essential for safe and efficient cataract surgery. The degree of dilation of the pupil is under the control of parasympathetic (sphincter muscle of iris) and sympathetic nervous system (dilator muscle of iris). Dilation is commonly achieved in the clinical environment by the sympathetic agonist phenylephrine and the parasympathetic antagonist tropicamide.

The authors report the results of this observational study, wherein the topical mydriatics such as Phenylephrine 10%, Tropicamide 1% and a commercially available combination of Tropicamide 0.8% and Phenylephrine 5% were compared with respect to efficacy, sustainability and safety while performing manual small incision cataract surgery (MSICS) under peribulbar anaesthesia.

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MATERIALS AND METHODS

This study was conducted at a tertiary care hospital in the Department of Ophthalmology in Maharashtra. The study has received approval from the Hospital Ethics Committee before the commencement of the study to ensure all patient data was handled with the highest standards of ethical integrity. The analysis was designed as a prospective, observational study with randomization. The duration of the study was from January 2024 to June 2024. After obtaining written informed consent, approximately 87 patients undergoing small incision cataract surgery (SICS) who met the inclusion criteria were enrolled in the study.

Inclusion Criteria: Patients diagnosed with senile cataract (according to the Lens Opacities Classification System LOCS III, with classification NO and NC 2–3),[9] of either gender and scheduled for surgery.

Exclusion Criteria: Patients with uveitis, glaucoma, alpha blocker use, topical or systemic use of nonsteroidal anti-inflammatory medication, prostaglandins, or miotics, corneal opacities, pupillary deformities, history of surgery on the same eye, diabetic retinopathy, history of heart disease, high blood pressure, or more than 0.25 mm of anisocoria prior to pupillary dilation and hypersensitivity to any component in medications.

Following tropicamide dilatation, all patients underwent slit lamp examination of the eyes to rule out posterior synechiae and uveitis. The patients who met the eligibility requirements were planned for manual small incision cataract surgery (MSICS). They were categorized into three groups, with computerized randomization carried out by the "blocked randomization method," which was tabled prior to the study. Patients were serially allocated into each group as and when recruitment occurred.

Pre-operatively, pupillary dilatation of patients of all the 3 groups was achieved with topical application of the planned mydriatic agent for 3 times, at 10 minutes interval, 30 minutes before the surgery. Every eye drop was put into the lower lid's conjunctival sac, and patients were instructed to close their eyes for about a minute following drop administration to avoid leakage through the punctum.

All research participants were given peribulbar anaesthesia, after which manual small incision cataract surgery was performed. Following the creation of the sclero-corneal tunnel, an anterior chamber (AC) entry was performed. Continuous curvilinear capsulorrhexis was completed with a 26 Gauge needle. Hydro-dissection was carried out, and the nucleus was delivered using visco-expression. The measurement of pupil diameter was done by placing Castroviejo calliper in front of the cornea, which could measure to a precision of 0.5 millimetres. The measurements were recorded at three different stages of cataract surgery; Stage I – Before AC entry, Stage II – After Capsulorrhexis and Stage III – After cataract extraction.

The data was compiled in Microsoft Excel and analyzed. Data from patients in the groups of Phenylephrine 10%, Tropicamide 1% and the commercially available combination of Tropicamide 0.8% and Phenylephrine 5% were described as frequency, percentage, mean values, and standard deviation. A paired T-test was used to determine differences in the pupillary diameter of the different groups. Statistical significance was established at a p value of < 0.05. The demographic data which included age, gender, laterality of the eye during surgery was compiled and compared between the groups. The study also recorded any adverse medication reactions that occurred following the application of topical mydriatics prior to surgery.

RESULTS

The research comprised of 87 eyes of 87 patients in total, divided into 3 groups with 29 patients being randomly assigned to each group. There were no significant side effects from the application of mydriatic eye drops that were reported prior to surgery. The demographic details of every category (Table 1) are depicted in the following table.

Table 1: Demographic characteristics of patients

Parameters	Tropicamide 1% (n=29)	Phenylephrine 10% (n=29)	Tropicamide 0.8% + Phenylephrine 5% (n=29)
Group	**A**	**B**	**C**
Age (years)			
Mean±SD	58±6.79	60±5.91	60±4.34
Gender			
Male	17(58%)	15(52%)	18(62%)
Female	12(42%)	14(48%)	11(38%)
Laterality of eye			
Right	14(48%)	16(55%)	10(34%)
Left	15(52%)	13(45%)	19(66%)

The mean intraoperative pupillary diameter in Tropicamide 1% group in Stage I- 7.66±0.66mm, Stage II – 6.43±1.45mm and Stage III – 5.78±0.45mm. The total loss of mydriasis is 1.88±1.05mm (24%). The mean intraoperative pupillary diameter in Phenylephrine 10% group in Stage I – 6.89±1.26mm, Stage II – 5.54±0.45mm and Stage III – 4.74±0.78mm. The total loss of mydriasis is 2.11±0.63 (28%). The mean intraoperative pupillary diameter in combination group Tropicamide 0.8% + Phenylephrine 5% in Stage I – 8.34±0.56mm, Stage II – 7.67±1.13mm and Stage III – 7.23±0.78mm. The total loss of mydriasis is 1.11±0.83 (13%).

Table 2: Pupillary Diameter during different stages of MSICS (mm)

Stages of pupil diameter measurement	Mean ± SD			P value
	Tropicamide 1%	Phenylephrine 10%	Tropicamide 0.8% + Phenylephrine 5%	
Before AC entry	7.66±0.66 mm	6.89±1.26 mm	8.34±0.56 mm	0.067
After Capsulorrhexis, nucleus delivery into AC	6.43±1.45 mm	5.54±0.45 mm	7.67±1.13 mm	0.061
After Cataract Extraction	5.78±0.45 mm	4.74±0.78 mm	7.23±0.78 mm	<0.05
Change from baseline	1.88±1.05	2.15±0.63	1.11±0.83	<0.05
Percentage of dilation loss	24.54%	28.74%	13.30%	<0.05

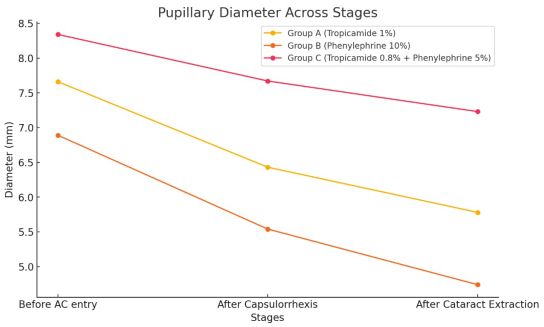

Fig. 1: Effect of Topical Mydriatics during different stages of MSICS

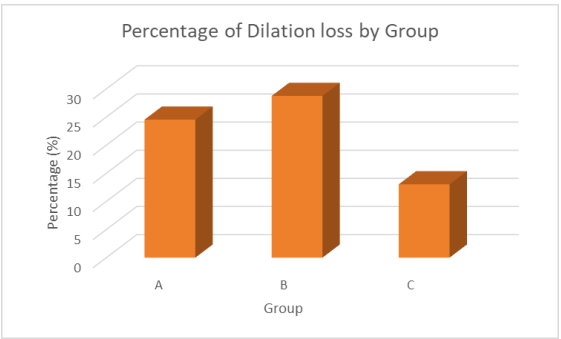

Fig. 2: Percentage of Dilation loss by groups

DISCUSSION

The study aimed to evaluate the efficacy, sustainability, and safety of commonly used topical mydriatics- tropicamide 1%, phenylephrine 10%, and a commercially available combination of tropicamide 0.8% and phenylephrine 5%—in achieving and maintaining adequate pupil dilation during manual small incision cataract surgery (MSICS). The results indicate that the combination of tropicamide 0.8% and phenylephrine 5% provides superior and a sustained mydriasis compared to the higher-concentration standalone agents, tropicamide 1% and phenylephrine 10%.

Adequate pupil dilation is critical for safe and effective cataract surgery. The pupil must remain dilated throughout the procedure to allow proper visualization of intraocular structures and safe manipulation of surgical instruments. A decrease in pupillary diameter, or "intraoperative miosis," complicates the procedure and increases the risk of surgical complications, such as iris prolapse, posterior capsule rupture, and damage to intraocular tissues. This observation aligns with findings from Lundberg et al. (2007), who reported that insufficient dilation during phacoemulsification was associated with an increased risk of iris trauma and incomplete nucleus removal, emphasizing the need for sustained mydriasis. [10]

The findings of this study highlight a significant advantage of using a combination of tropicamide and phenylephrine at lower concentrations. The group receiving the combination (Group C) demonstrated only a 13% reduction in pupillary dilation after cataract extraction, compared to 24.5% in the tropicamide 1% group (Group A) and 29% in the phenylephrine 10% group (Group B). This suggests that the combination of a parasympatholytic (tropicamide) and a sympathomimetic (phenylephrine) at reduced strengths provides a synergistic effect, ensuring optimal dilation and better sustainability throughout the procedure. Saenz-de-Viteri et al. (2020) supported this finding, reporting that combination drops yielded better intraoperative outcomes, with reduced incidence of miosis compared to standalone agents. [11]

Standalone tropicamide 1% showed significant intraoperative miosis, particularly after capsulorrhexis and cataract extraction. Tropicamide, a parasympatholytic agent, blocks muscarinic receptors in the sphincter pupillae, leading to relaxation and dilation. However, its effects may wane during prolonged surgeries, especially as it does not address the contribution of the sympathetic nervous system. Similarly, phenylephrine 10%, a sympathomimetic that stimulates alpha-adrenergic receptors in the dilator pupillae, also demonstrated a greater loss of dilation during the procedure. Phenylephrine alone does not block the parasympathetic constriction reflex, which may explain its reduced sustainability. Wong et al. (2009) reported similar results, stating that standalone phenylephrine was less effective in maintaining sustained dilation during longer surgeries. [12]

The synergistic action of the combination drops can be attributed to their dual mechanism of action. Tropicamide inhibits the parasympathetic constriction reflex, while phenylephrine enhances dilation by stimulating the

sympathetic pathway. The lower concentrations used in the combination drops may also reduce the risk of systemic side effects, such as cardiovascular complications, which are a known concern with higher doses of phenylephrine. Bucci et al. (2004) emphasized that lower concentrations of phenylephrine combined with tropicamide achieved adequate mydriasis while minimizing the risk of adverse cardiovascular events.[13]

Another notable observation was the safety profile of the combination drops. None of the patients in Group C reported significant adverse effects, underscoring the tolerability of the lower-concentration combination. This is particularly relevant in resource-limited settings, where patient safety and cost-effectiveness are of paramount importance. Shastri et al. (2018) similarly concluded that combination mydriatics not only enhanced efficacy but also improved safety outcomes, making them a practical choice for routine use.[14]

The implications of these findings are significant for surgical practice, especially in high-volume cataract surgery programs. The combination of tropicamide 0.8% and phenylephrine 5% offers a cost-effective and safer alternative to higher-concentration standalone agents, improving surgical outcomes while minimizing the risk of complications. This is especially relevant in developing countries, where high-volume cataract surgeries are often performed in community-based settings. A study by Maheshwari et al. (2017) highlighted the critical role of affordable and effective mydriatics in such programs, as they directly impact surgical efficiency and patient outcomes.[15]

CONCLUSION

The combination of tropicamide 0.8% and phenylephrine 5% is superior in achieving and maintaining pupil dilation during cataract surgery, offering a safer and more effective alternative to higher-concentration standalone mydriatics. These findings have significant implications for improving the safety and efficacy of cataract surgery, particularly in settings where high-volume surgical interventions are performed. The study concludes the safety profile with sustainable results of these mydriatic agents.

This study was conducted on a relatively small sample size, which may limit the generalizability of the findings. Future studies with larger sample sizes and a multicentric design could provide more robust evidence. Additionally, the impact of other factors such as patient age, systemic comorbidities, and duration of surgery on the efficacy of these agents warrants further investigation.

Acknowledgments

This study was conducted in the Department of Ophthalmology at Vedantaa Institute of Medical Sciences, Palghar. We are grateful for the support received from the institution's authorities and staff, especially our Dean Dr. Shubhangi Parkar and Ethics Committee Secretary Dr. Sunil Kuyare. We also extend our thanks to all the Ophthalmology nursing staff for their assistance and encouragement during the course of this study.

REFERENCES

1. Steinmetz JD. Causes of blindness and vision impairment in 2020 and trends over 30 years, and prevalence of avoidable blindness in relation to VISION 2020: the Right to Sight: an analysis for the Global Burden of Disease Study. *The Lancet Global Health*. 2021;9(2):e144–e160. Available from: https://doi.org/10.1016/s2214-109x(20)30489-7.
2. Thomas R. Role of small incision cataract surgery in the Indian scenario. *Indian Journal of Ophthalmology*. 2009;57(1):1–2. Available from: https://doi.org/10.4103/0301-4738.44485.
3. Gogate PM. Small incision cataract surgery: Complications and mini-review. *Indian Journal of Ophthalmology*. 2009;57(1):45–49. Available from: https://doi.org/10.4103/0301-4738.44512.
4. Tabin G, Chen M, Espandar L. Cataract surgery for the developing world. *Current Opinion in Ophthalmology*. 2008;19(1):55–59. Available from: https://doi.org/10.1097/icu.0b013e3282f154bd.
5. Gogate PM, Deshpande M, Wormald RP, Deshpande R, Kulkarni SR. Extracapsular cataract surgery compared with manual small incision cataract surgery in community eye care setting in Western India: A randomised controlled trial. *British Journal of Ophthalmology*. 2003;87(6):667–672. Available from: https://doi.org/10.1136/bjo.87.6.667.
6. Venkatesh R, Muralikrishnan R, Balent LC, Prakash SK, Prajna NV. Outcomes of high volume cataract surgeries in a developing country. *British Journal of Ophthalmology*. 2005;89(9):1079–1083. Available from: https://doi.org/10.1136/bjo.2004.063479.
7. Gogate P. Comparison of various techniques for cataract surgery, their efficacy, safety, and cost. *Oman Journal of Ophthalmology*. 2010;3(3):105–106. Available from: https://doi.org/10.4103/0974-620X.71880.
8. Salmon JF. Kanski's Clinical Ophthalmology E-Book: A Systematic Approach. 9th ed. Elsevier Health Sciences. 2019. Available from: https://shop.elsevier.com/books/kanskis-clinical-ophthalmology/salmon/978-0-7020-7711-1.
9. Chylack LT, Wolfe JK, Singer DM, Leske MC, Bullimore MA, Bailey IL, et al. The lens opacities classification system, version III (LOCS III). *Archives of Ophthalmology*. 1993;111(6):831–836. Available from: https://doi.org/10.1001/archopht.1993.01090060119035.
10. Lundberg B, Behndig A. Intracameral mydriatics in phacoemulsification surgery obviate the need for epinephrine irrigation. *Acta Ophthalmologica Scandinavica*. 2007;85(5):546–550. Available from: https://doi.org/10.1111/j.1600-0420.2007.00892.x.
11. Saenz-De-Viteri M, Vergés C. The efficacy of combined mydriatic agents in maintaining dilation during phacoemulsification. *European Journal of Ophthalmology*. 2020.
12. Wong R, Chan T. Comparative study of phenylephrine and tropicamide for surgical mydriasis. *Ophthalmic Surgery, Lasers, and Imaging*. 2009.
13. Bucci FA, Fluet AT. Safety and efficacy of reduced-strength phenylephrine in combination with tropicamide for pupil dilation. Journal of Cataract & Refractive Surgery. 2004.
14. Shastri M, Patel R. Efficacy and safety of combined mydriatics in cataract surgery: A community-based study. *Indian Journal of Ophthalmology*. 2018.
15. Maheshwari R, Ramaswamy S. Role of affordable mydriatic combinations in high-volume cataract surgeries. Asian Journal of Ophthalmology. 2017.