Journal of Population Therapeutics & Clinical Pharmacology

RESEARCH ARTICLE
DOI: 10.53555/09757g45

SAFETY OF AN INTRACAMERAL FIXED COMBINATION (MYDORIA) FOR MYDRIASIS AND INTRAOCULAR ANESTHESIA DURING CATARACT SURGERY: A COMPARATIVE STUDY

Dr. Md. Sanwar Hossain[1*], Dr. Md. Arifuzzaman[2], Dr. Mohammad Mazaharul Islam[3], Dr. Md. Golam Faruk Hossain[4], Dr. Muktar Ali[5], Dr. Tasnim Khanom[6]

[1*]Assistant Professor, Department of Ophthalmology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh
[2]Vitreo-Retina Consultant, Department of Ophthalmology, Bangladesh Eye Hospital, Dhaka, Bangladesh
[3]Medical officer, Department of Community Ophthalmology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh
[4]Assistant Professor, Department of Community Ophthalmology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh
[5]Senior Consultant, Department of Ophthalmology, Eye Care Hospital, Mali, Maldives
[6]Medical officer, Department of Ophthalmology, BIRDEM General Hospital, Dhaka, Bangladesh

***Corresponding Author:** Dr. Md. Sanwar Hossain
*Assistant Professor, Department of Ophthalmology, Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka, Bangladesh

Abstract

Background: Effective mydriasis and intraoperative anesthesia are critical for successful phacoemulsification cataract surgery. Traditional topical regimens often require multiple preoperative applications and may cause ocular surface irritation or postoperative complications. Intracameral fixed combinations offer a streamlined alternative that may enhance surgical efficiency and patient comfort. **Aim of the study:** To compare the safety profile of an intracameral fixed combination of mydriatics and anesthetic (ICMA) with the standard topical mydriatic regimen in patients undergoing phacoemulsification cataract surgery.

Methods: This comparative observational study was conducted in the Department of Ophthalmology at Bangabandhu Sheikh Mujib Medical University (BSMMU) over a 12-month period from August 2016 to July 2017. A total of 150 adult patients diagnosed with age-related cataracts and scheduled for routine phacoemulsification surgery were enrolled following informed written consent. Patients were divided equally into ICMA and Topical mydriatic regimen groups (n=75 each).

Result: There was no statistically significant difference in demographic characteristics between the two groups. Intraoperatively, the ICMA group had a larger pupil (6.8±0.5 mm vs. 6.2±0.6 mm; $p<0.01$), fewer cases of constriction (6.7% vs. 18.7%; $p=0.02$), and less need for additional mydriatics (4% vs. 16%; $p=0.01$). Post-op IOP at 1 hour was lower in ICMA (15.2±2.4 mmHg vs. 16.6±2.8; $p=0.01$). ICMA showed less pain (1.3% vs. 9.3%; $p=0.03$) and endothelial cell loss (5.1% vs. 5.7%; $p=0.04$).

Conclusion: The study concludes that intracameral fixed combinations of mydriatics and anesthetic offer a safer and more effective alternative to traditional topical Mydriatic regimens in cataract surgery.

Keywords: Safety, Intracameral Fixed Combination (Mydoria), Mydriasis, Intraocular Anesthesia, and Cataract Surgery

INTRODUCTION

Cataract remains the leading cause of avoidable blindness worldwide, posing a substantial burden on global public health, particularly in low- and middle-income countries. Cataract accounted for 33.4% of all global blindness and 18.4% of moderate to severe visual impairment in 2010, underscoring its persistent significance despite declining age-standardized prevalence.[1] Despite advancements in surgical techniques and access to ophthalmic care, the burden remains especially high in South and Southeast Asia.[1] The global importance of cataract surgery is equally reflected in its frequency. It is now the most commonly performed ophthalmic procedure worldwide, with an estimated 15 to 20 million surgeries conducted annually.[2] In industrialized nations, cataract surgery has become a highly refined, cost-effective, and outcomes-oriented intervention. More importantly, it delivers measurable improvements not only in visual acuity but also in patient-reported quality of life, mental health, and daily functioning.[3] However, access to cataract surgery remains highly inequitable across and within countries. Rural populations are significantly more likely to suffer from untreated cataracts and face lower surgical coverage, often due to limited ophthalmic infrastructure and socioeconomic constraints.[1] Gender-based disparities further exacerbate this challenge; studies indicate that blindness prevalence could be reduced by up to 11% globally if women received cataract surgeries at the same rate as men.[4] This uneven distribution of surgical services continues to hinder global efforts to eliminate cataract-related blindness. Within the surgical procedure itself, achieving and maintaining adequate mydriasis and intraocular anesthesia are critical to the success, safety, and efficiency of cataract extraction. Sufficient pupil dilation enables better visualization of the lens and reduces the risk of complications such as posterior capsule rupture, iris trauma, and retained lens fragments. Similarly, intraocular anesthesia plays an essential role in maintaining patient comfort and controlling intraoperative pain, especially during phacoemulsification.[5,6] The traditional approach to achieving mydriasis involves the preoperative topical administration of agents such as phenylephrine, tropicamide, and cyclopentolate, often requiring repeated doses over 30 to 60 minutes before surgery.[5] Anesthesia is typically provided via topical lidocaine drops or gels, sometimes supplemented with intracameral injections. However, these conventional topical regimens are fraught with several limitations. The onset of action is often delayed and inconsistent, and the depth and duration of mydriasis can vary substantially among patients due to age-related or pharmacogenomic factors.[7] Repeated instillation by nursing staff can strain preoperative workflow and increase the risk of dosing errors. Furthermore, topical agents such as phenylephrine may be absorbed systemically, potentially inducing cardiovascular side effects, particularly in elderly or vulnerable patients.[8,9] There is also evidence that prolonged exposure to topical agents can compromise the ocular surface, causing epitheliopathy or irritation, which may affect surgical outcomes or patient satisfaction. As such, alternative delivery methods that provide rapid, sustained, and safer effects are being actively explored. In recent years, intracameral administration of mydriatics and anesthetics has emerged as a promising approach that addresses many of the limitations associated with topical delivery. By delivering medication directly into the anterior chamber at the start of surgery, this method ensures rapid onset and sustained intraoperative action with minimal systemic exposure.[10] Fixed-combination agents such as Mydoria, comprising phenylephrine 0.31%, tropicamide 0.02%, and lidocaine 1%, offer the added benefit of combining both mydriatic and anesthetic effects into a single, precisely administered dose. Early data suggest favorable safety profiles and adequate mydriatic efficacy, but comparative studies evaluating the safety of Mydoria versus standard regimens remain limited in number and scope. Given this context, the present study seeks to evaluate the safety profile of the fixed intracameral combination Mydoria in comparison to traditional topical or other intracameral methods.

OBJECTIVES

To compare the safety profile of an intracameral fixed combination of mydriatics and anesthetic (ICMA) with the standard topical mydriatic regimen in patients undergoing phacoemulsification cataract surgery.

METHODOLOGY & MATERIALS

This comparative observational study was conducted in the Department of Ophthalmology at Bangabandhu Sheikh Mujib Medical University (BSMMU) over a 12-month period from August 2016 to July 2017. A total of 150 adult patients diagnosed with age-related cataracts and scheduled for routine phacoemulsification surgery were enrolled following informed written consent. Participants were divided into two equal groups of 75 each: the ICMA group received an intracameral fixed combination of mydriatics and anesthetic (containing phenylephrine 0.31%, tropicamide 0.02%, and lidocaine 1%) administered at the beginning of surgery, while the Topical Mydriatic group received the standard preoperative regimen of topical mydriatics and anesthetic agents (including phenylephrine 2.5%, tropicamide 1%, and lidocaine gel). Patients with prior intraocular surgery, pseudo exfoliation, ocular inflammation, or known hypersensitivity to any of the study drugs were excluded. All surgeries were performed using a standard phacoemulsification technique by experienced ophthalmic surgeons under aseptic conditions. Key intraoperative and postoperative outcomes, including pupil diameter maintenance, need for additional mydriatics, intraocular pressure (IOP) fluctuations, postoperative pain, endothelial cell loss, and adverse events were recorded and analyzed. Data were compiled using structured case report forms and subjected to statistical analysis using appropriate parametric and non-parametric tests, with a significance threshold set at $p < 0.05$.

RESULT

Table I presents the baseline demographic and clinical characteristics of the two study groups, each comprising 75 patients. Both groups were well matched in terms of age, with a mean of 66.2 ± 8.3 years in the ICMA group and 65.8 ± 9.1 years in the Topical Mydriatic group (p=0.72). Gender distribution showed a slight male predominance in both groups-50.7% in the ICMA group and 54.7% in the Topical Mydriatic group (p=0.65). The laterality of surgeries was also similar, with right eye procedures comprising 52% and 56% in the ICMA and Topical Mydriatic groups, respectively (p=0.59). Baseline intraocular pressure (IOP) and preoperative pupil diameter were statistically comparable between groups (p=0.38 and p=0.47, respectively). Table II outlines the intraoperative parameters and highlights significant differences between the groups. The mean pupil size during surgery was significantly larger in the ICMA group (6.8 ± 0.5 mm) compared to the Topical Mydriatic group (6.2 ± 0.6 mm, p<0.01). The incidence of intraoperative pupil constriction was significantly lower in the ICMA group (6.7%) than in the Topical Mydriatic group (18.7%, p=0.02). Additionally, the need for supplemental mydriatic agents was substantially reduced in the ICMA group (4%) versus the Topical Mydriatic group (16%, p=0.01). Intraoperative complications were infrequent and not significantly different between the groups (p=0.41). Table III compares postoperative IOP changes between the groups at various time points. A statistically significant difference was observed 1 hour after surgery, with the Topical Mydriatic group exhibiting a higher IOP (16.6 ± 2.8 mmHg) compared to the ICMA group (15.2 ± 2.4 mmHg, p=0.01). However, by Day 1 and Day 7 postoperatively, the IOP levels had returned to comparable values between both groups (p=0.45 and p=0.40, respectively). Table IV summarizes postoperative outcomes. Although corneal edema and anterior chamber reactions occurred less frequently in the ICMA group, the differences were not statistically significant (p=0.14 and p=0.24, respectively). A significantly lower proportion of patients in the ICMA group reported postoperative pain (1.3%) compared to the Topical Mydriatic group (9.3%, p=0.03). Endothelial cell loss was also significantly lower in the ICMA group (5.1 ± 1.2%) versus the Topical Mydriatic group (5.7 ± 1.5%, p=0.04), suggesting better preservation of corneal integrity with intracameral administration.

Table I: Baseline demographic and clinical characteristics of the study groups (N=150)

Variable	ICMA Group (n=75)	Topical Mydriatic Group (n=75)	p-value
Age (Years)			
Mean ± SD	66.2 ± 8.3	65.8 ± 9.1	0.72
Gender			
Male	38 (50.7%)	41 (54.7%)	0.65
Female	37 (49.3%)	34 (45.3%)	
Site of surgery			
Right Eye	39 (52%)	42 (56%)	0.59
Left Eye	36 (48%)	33 (44%)	
Baseline IOP (mmHg			
(Mean ± SD)	14.5 ± 2.1	14.8 ± 2.3	0.38
Pupil Diameter (mm)			
Mean ± SD	3.1 ± 0.4	3.0 ± 0.5	0.47

Table-II: Comparison of the intraoperative parameters between the study groups (N=150)

Parameter	ICMA Group (n=75)	Topical Mydriatic Group (n=75)	p-value
Pupil Size During Surgery (mm)			
Mean ± SD	6.8 ± 0.5	6.2 ± 0.6	<0.01
Pupil Constriction Noted	5 (6.7%)	14 (18.7%)	0.02
Use of Additional Mydriatics	3 (4%)	12 (16%)	0.01
Intraoperative Complications	2 (2.7%)	4 (5.3%)	0.41

Table-III: Comparison of the postoperative Intraocular Pressure (IOP) changes between the study groups (N=150)

Time Point	ICMA Group (IOP mmHg ± SD)	Topical Mydriatic Group (IOP mmHg ± SD)	p-value
Preoperative	14.5 ± 2.1	14.8 ± 2.3	0.38
1 Hour Post-op	15.2 ± 2.4	16.6 ± 2.8	0.01
Day 1 Post-op	14.6 ± 2.0	14.9 ± 2.2	0.45
Day 7 Post-op	14.2 ± 1.9	14.5 ± 2.1	0.4

Table-IV: Comparison of the postoperative outcome between the study groups (N=150)

Outcome	ICMA Group (n=75)	Topical Mydriatic Group (n=75)	p-value
Corneal Edema	4 (5.3%)	9 (12%)	0.14
Anterior Chamber Reaction	2 (2.7%)	5 (6.7%)	0.24
Pain Reported	1 (1.3%)	7 (9.3%)	0.03
Endothelial Cell Loss (%)	5.1 ± 1.2	5.7 ± 1.5	0.04

DISCUSSION

The current observational study aimed to evaluate the safety and efficacy of an intracameral fixed combination of mydriatics and anesthetic (ICMA) versus a standard topical Mydriatic regimen during cataract surgery, focusing on intraoperative performance and postoperative outcomes. Baseline demographic and clinical characteristics of both groups were well matched, minimizing selection bias. Parameters such as age, gender distribution, laterality of surgery, baseline intraocular pressure (IOP), and preoperative pupil diameter showed no statistically significant differences, thereby ensuring comparable conditions for evaluating the effects of the two intervention protocols. This consistency is in line with previous research that emphasized the importance of balanced demographic profiles when comparing different drug administration routes in cataract surgery.[11,12] Intraoperatively, the ICMA group demonstrated a clear advantage, with significantly larger pupil

sizes maintained throughout surgery (6.8 ± 0.5 mm vs. 6.2 ± 0.6 mm; p<0.01). The incidence of pupil constriction and the need for additional mydriatic agents were also significantly lower in this group. The reduced incidence of intraoperative pupil constriction (6.7% in ICMA vs. 18.7% in Topical) further supports the intraoperative reliability of the ICMA combination. These outcomes align with previous research indicating superior intraoperative pupil stability with intracameral use.[13,14] Grob and Gonzalez-Gonzalez[5] also reported that intracameral administration produced rapid and sustained mydriasis while minimizing the pharmacologic load on the ocular surface. Although intraoperative complication rates were low in both groups, their incidence did not significantly differ. This supports prior findings that intracameral drug delivery, when properly administered, does not elevate surgical risk.[5,15] Importantly, the ICMA approach avoided repeated topical exposure and reduced handling of the ocular surface, factors previously linked with increased surgical complexity and infection risk.[16] Postoperatively, a transient IOP elevation was observed in the Topical Mydriatic group at one hour (16.6 ± 2.8 mmHg vs. 15.2 ± 2.4 mmHg; p=0.01), though this difference resolved by Day 1 and Day 7. This early IOP spike is consistent with reports by Hovanesian et al.[17], who observed elevated IOP following topical regimens due to fluid retention and mechanical blockage at the trabecular meshwork. In contrast, intracameral drug use, as demonstrated in the current study, resulted in a more stable early postoperative IOP profile, likely owing to lower cumulative drug volume and reduced ocular surface disturbance.[16] Postoperative outcomes further favored the ICMA protocol. Although corneal edema and anterior chamber reactions were observed less frequently in the ICMA group, these differences did not reach statistical significance. However, the incidence of reported postoperative pain was significantly lower in the ICMA group (1.3% vs. 9.3%; p=0.03). These findings resonate with Grob and Gonzalez-Gonzalez[5], who identified decreased ocular pain and inflammation with intracameral phenylephrine-ketorolac combinations. Similarly, Lofoco et al.[15] reported reduced corneal endothelial damage when intracameral anesthesia was applied judiciously. Shah et al.[14] also suggested that intracameral routes preserve corneal health better than topical regimens due to more controlled pharmacokinetics and localized action. Endothelial cell preservation is particularly significant, as excessive loss can predispose patients to corneal decompensation. The significantly lower endothelial cell loss in the ICMA group (5.1 ± 1.2%) compared to the Topical group (5.7 ± 1.5%) supports previous results by Lundberg and Behndig[10], who showed that intracameral mydriatics caused minimal endothelial trauma. Additionally, the reduced pain perception observed in our ICMA group parallels outcome noted by Grob and Gonzalez-Gonzalez[5], who associated intracameral phenylephrine-lidocaine combinations with improved patient-reported comfort. All these findings support the growing preference for intracameral mydriatic-anesthetic combinations as a safer and more effective alternative to conventional topical Mydriatic regimens in cataract surgery.

Limitations of the study

In our study, there was small sample size and absence of control for comparison. Study population was selected from one center in Dhaka city, so may not represent wider population. The study was conducted at a short period of time.

CONCLUSION AND RECOMMENDATIONS

The study concludes that intracameral fixed combinations of mydriatics and anesthetic offer a safer and more effective alternative to traditional topical Mydriatic regimens in cataract surgery. ICMA provided superior intraoperative mydriasis, reduced the need for supplemental agents, and minimized postoperative pain and endothelial cell loss. These benefits, coupled with comparable complication rates, highlight ICMA's potential to enhance surgical outcomes and patient comfort. Further large-scale studies are recommended to validate these findings across diverse patient populations and clinical settings.

REFERENCES

1. Khairallah M, Kahloun R, Bourne R, Limburg H, Flaxman SR, Jonas JB, Keeffe J, Leasher J, Naidoo K, Pesudovs K, Price H. Number of people blind or visually impaired by cataract

worldwide and in world regions, 1990 to 2010. Investigative ophthalmology & visual science. 2015 Oct 1;56(11):6762-9.
2. Stürmer J. Cataracts—Trend and new developments. Spektrum Augenheilkd. 2009;23(4):171–5.
3. Lamoureux EL, Fenwick E, Pesudovs K, Tan D. The impact of cataract surgery on quality of life. Current opinion in ophthalmology. 2011 Jan 1;22(1):19-27.
4. Lewallen S, Mousa A, Bassett K, Courtright P. Cataract surgical coverage remains lower in women. Br J Ophthalmol. 2008;93(3):295–8.
5. Grob SR, Gonzalez-Gonzalez LA, Daly MK, Yoo SH. Management of mydriasis and pain in cataract and intraocular lens surgery: Survey of ASCRS members and literature review. J Cataract Refract Surg. 2014;40(5):858–65.
6. Westborg I, Mönestam E. Intracameral anesthesia for cataract surgery: A population-based study of safety and patient satisfaction. J Cataract Refract Surg. 2012;38(8):1415–20.
7. Jariyanoravisse B, Sripong P, Panyawatananukul E. The number of mydriatic instillations on pupillary size in cataract patients. Thai J Ophthalmol. 2012;26(2).
8. Morgado AA, Barros JDM, Moraes LV. Comparative study of mydriasis in cataract surgery: Topical versus intracameral. Arq Bras Oftalmol. 2010;73(5):421–5.
9. Greher M, Hartmann B, Pöstinger A. Hypertension and pulmonary edema associated with ophthalmic use of phenylephrine in infants. Anesthesiology. 1998;89(3).
10. Lundberg B, Behndig A. Intracameral mydriatics in phacoemulsification cataract surgery. J Cataract Refract Surg. 2003;29(12):2366–71.
11. Hovanesian JA, Sheppard JD, Trattler WB, Gayton JL, Malhotra RP, Schaaf DT, Ng E, Dunn SH. Intracameral phenylephrine and ketorolac during cataract surgery to maintain intraoperative mydriasis and reduce postoperative ocular pain: integrated results from 2 pivotal phase 3 studies. Journal of Cataract & Refractive Surgery. 2015 Oct 1;41(10):2060-8.
12. Westborg I, Mönestam E. Intracameral anesthesia for cataract surgery: a population-based study on patient satisfaction and outcome. Clinical Ophthalmology. 2013 Oct 16:2063-8.
13. Behndig A, Korobelnik JF. Mydriatic insert and intracameral injections compared with mydriatic eyedrops in cataract surgery: Controlled studies. J Cataract Refract Surg. 2015.
14. Shah A, Johal S, Lee N. Mydriasert pupillary dilation for cataract surgery: An economic and clinical study. BMC Ophthalmol. 2015;15:118.
15. Lofoco G, Ciucci F, Bardocci A, Quercioli P. Efficacy of topical plus intracameral anesthesia for cataract surgery in high myopia: Randomized controlled trial. J Cataract Refract Surg. 2008.
16. Ismail R, Sallam A. Complications associated with cataract surgery. Cataract Surgery. 2013 Feb 7.
17. Hovanesian JA, Sheppard JD, Trattler WB. Intracameral phenylephrine and ketorolac during cataract surgery to maintain intraoperative mydriasis and reduce postoperative ocular pain: Integrated analysis. J Cataract Refract Surg. 2015.