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Efficacy of Intracameral versus Topical Mydriatics in Phacoemulsification Surgery – A Randomized Controlled Trial

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A B S T R A C T

Purpose*:** To compare the efficacy of an intracameralmydriatic agent with a topicalmydriatic eye drop during phacoemulsification cataract surgery.Methods*:** All the patients with age group between 40 to 80 years with immature senile cataract, who came to the Ophthalmology OPD & were posted for surgery, were randomized into two groups. One group received topical mydriatics (Group-A) & the other group received intracameralmydriatic (Group-B), for pupil dilation prior to surgery. Parameters compared among both the groups,werethe size of pupilat different time points during the surgery;the onset of action of mydriasis& mean changes of variation in the pulse rate, systolic & diastolic blood pressures, at various time points during the surgery.***Result*:** A total of 204 patients were enrolled in this study, who were randomly divided among both the groups (102 each). In Group-A, it was observed that the mean pupil size was maximum at 30 minutes after the start of topical drug administration i.e.-(7.81 +/-1.03) mm.; which gradually decreased towards the end of surgery. Whereas, in Group-B, the pupil size measured during the same time was (7.45 +/-0.81) mm., which also decreased gradually towards the end of surgery. But, following nucleus removalfrom the anterior chamber &corticalaspiration, the mean pupil size in Group-B was observed to be (6.45 +/-0.91) mm., which was greater than that of Group-A, i.e.-(6.01 +/-0.70)mm. Also, the time duration for which the pupil was larger during the surgery was found to be better in Group-B, compared to Group-A. Moreover, blood pressure & pulse rate, measured during various time points during the surgery, were observed to be within the permissible limits in both the groups.***Conclusion*:** Intracameralmydriasis is a rapid, safe & effective alternative for pupil dilatation, during cataract surgery, with lesser systemic side effects; compared to the traditional topical eye drops.

Keywords: Cataract,miosis,mydriasis,topical,intracameral.

ABBREVIATIONS:

ICMA: Intra-Cameral Mydriatic Agent; **IMSC**: Immature Senile Cataract; **IOL**: Intra-Ocular Lens; **PCIOL**: Posterior Chamber Intra-Ocular Lens; **CCC**: Continuous Curvilinear Capsulorhexis; **DM**: Diabetes Mellitus; **IFIS**: Intra-Operative Floppy Iris Syndrome; **PXF**: Pseudo-Exfoliative Syndrome; **IOP**: Intra-Ocular Pressure; **SBP**: Systolic Blood Pressure; **DBP**: Diastolic Blood Pressure; **PR**: Pulse Rate.

INTRODUCTION:

Blindness, due to cataract, is a remarkable problem around the world, particularly in the developing countries, like India [1]. It has resulted in cataract surgery, being one of the most commonly undertaken surgical procedures around the globe. Moreover, there is good evidence to show that extraction of the cataractous lens, followed by implantation of an IOL, is one of the most beneficial procedures to improve a patient's quality of life [2].

For a successful cataract surgery, a pupil diameter of 7 to 8 mm. is an absolute necessity [2]; because, an adequately dilated pupil not only facilitates intra-operative manipulation, but also reduces complications [2].

However, there may be an unforeseeable pupillary constriction in the midst of surgery, as a result of unintended instrument contact with the iris, illumination of the surgical microscope, etc.; which can lead to a number of intra-

operative complications, including iris damage, incomplete removal of cortico-nuclear material and/or viscoelastic substance from the anterior chamber, posterior capsular rupture (PCR), vitreous loss [3]; which would further lead to a prolonged duration of surgery, increasing the risk of post-operative complications, like endophthalmitis.

Over the years & still today, topical eye drops have been routinely used for pupil dilation (mydriasis), prior to cataract surgery [4]; which is a combination of a topical sympathomimetic (Phenylephrine) &a para-sympatholytic (Tropicamide, Cyclopentolate) agent. But this regimen has many drawbacks; which may lead to inconsistent mydriasis or intra-operative miosis; especially, in patients with IFIS [2, 5] & DM [5]. Furthermore, the topical medication must penetrate a complex physiological corneal matrix; including a lipid-rich hydrophobic epithelium, a hydrophilic stroma&a hydrophobic endothelium.As a result of low bio-availability, there is a delay in the onset of mydriasis. Moreover, it may also cause cardio-vascular adverse effects, via systemic absorption, through the nasal mucosa [6].

Therefore, in order to find new methods of pupil dilation, various methods have been explored. After undergoing multiple trial & studies, it has been found that ICMA is a safe & effective alternative to topical mydriatic eye drops [7]; as it effectively avoids the issues of poor bio-availability, prolonged duration of action, corneal epithelial toxicity; associated with topical agents & provides almost instant action [8].

First reported in 2003, intracameral mydriatics are a combination of Tropicamide (0.02%), Phenylephrine (0.31%) &Lidocaine (1.0%), without any added preservative [9]; with a rapid onset of action&a stable intra-operative mydriasis; which proves to be relatively safe& an effective methodof pupil dilation& with minimal systemic side-effects.

We have undertaken this study because a relatively smaller number of studies have been done around the world & in India too.This study wouldfurther assist in completing the existing lacunae in the already available information regarding this relatively new technique of pupil dilation during cataract surgery.

Materials and Methods:

This prospective, interventional study was conducted atthe Department ofOphthalmology, Rohilkhand Medical College & Hospital, Bareilly (Uttar Pradesh); from 1st. November (2022) to 31st. October (2023), in a total of 204 patients.

Inclusion Criteria:

1) Patients aged 40 to 80 years, with IMSC, in oneor both the eyes, giving an informed consent & who were scheduled to undergo phacoemulsification with PCIOL implantation.
2) Pupil diameter of at least 6 to 7mm. had to be obtained within 30 minutes, following instillation of one drop of topical mydriatic.

Exclusion Criteria:

1) History of previous intra-ocular surgery in ipsilateral eye.
2) Patients with co-existing ocular pathologies in ipsilateral eye.
3) History of trauma, infection or inflammation to ipsilateral eye, within the previous three months.
4) Patients with poorly dilating pupils as a result of DM, IFIS, PXF syndrome, senile miosis& patients with prolonged pilocarpine therapy.
5) Congenital cataract.
6) Mature cataracts or associated raised IOP.

METHODOLOGY:

After taking approval from the Institutional Ethical Committee (IEC) &Clinical Trials Registry of India (CTRI), the study was conducted by recruitingpatients, qualifying the inclusion as well as exclusion criteria. The patientswereprovided with both written & oral information, as well as a signed written consent was obtained from each patient, before enrolment into the study.

A detailed history, taken from the guardian or patient, was written down.A detailed ocular & general examination were done and recorded on the proforma as well.

After undergoing all the necessary pre-operative work-up (BCVA, slit-lamp examination of the anterior segment, tonometry, auto-refractokeratometry, A-scan, B-scan, dilated fundus evaluation by ophthalmoscopy), the patients, satisfying the inclusion criteria, were randomized into 2 groups: Group-A (102) & Group-B (102). Patients in Group-A received topical mydriatic drops (Tropicamide - 0.8% W/V &Phenylephrine - 5% W/V); those in Group-B received intracameralmydriatic injection (Tropicamide - 0.02%, Phenylephrine - 0.31% and Lidocaine - 1%). Parameters

to be compared, among both the groups, were the onset of action of mydriasis, maximum pupil size attained during the surgery& systemic effects (blood pressure & pulse rate).

The pupil size was measured, in millimeter (mm), using Castroviejo'scaliper, in both thegroups, at four time points during the surgery:

1) **T-0**: Prior to drug administration.
2) **T-1**: 30 minutes after topical drug administration (Group-A) & 60 seconds after intracameral injection (Group-B).
3) **T-2**: Immediately prior to CCC (Continuous Curvilinear Capsulorhexis).
4) **T-3**: After aspiration of cortical matter from the anterior chamber.

Blood pressure (mmHg.) & pulse rate (bpm.) were measured, in both the groups, at three time points, during the surgery:

1) **T-0**: Before shifting to the OT.
2) **T-1**: 30 minutes after a topical drug administration (Group-A) & 60 seconds after an intracameral injection (Group-B).
3) **T-2**: Before shifting the patient to recovery.

RESULTS:

Table-1: Distribution of study participants on the basis of Age in both the groups.

Age group	Frequency		Percentage	
	Group-A	Group-B	Group-A	Group-B
(40-50) years	16	**51**	15.68%	**50.00%**
(50-60) years	30	33	29.41%	32.35%
(60-70) years	**36**	8	**35.29%**	7.84%
(70-80) years	20	10	19.60%	9.80%
Total:	102	102	100.00%	100.00%

Among the study participants, it has been observed that, in Group-A (topical), 35.29% (majority) of the population belonged to the age group of 60 to 70 years; 29.41% belonged to (50-60) years; 19.60% belonged to (70-80) years & 15.68% belonged to (40-50) years.

However, in Group-B (intracameral), 50% (majority) of the study participants belonged to the age group of 40 to 50 years; 32.35% belonged to (50-60) years; 9.80% belonged to (70-80) years & 7.84% belonged to (60-70) years.

Table-2: Distribution of study participants on the basis of Gender in both the groups.

Gender	Frequency		Percentage	
	Group-A	Group-B	Group-A	Group-B
Male	11	**52**	10.78%	**50.98%**
Female	**91**	50	**89.21%**	49.01%
Total:	102	102	100.00%	100.00%

Among the study participants, it has been observed that, in Group-A, 89.21% of the population were female; whereas, males constituted 10.78%.

However, in Group-B, 50.98% of the study participants were male; whereas, females constituted 49.01%.

Table-3: Distribution of study participants on the basis of Route of administration.

Type of route	Frequency	Percentage
Group-A	102	50.00%
Group-B	102	50.00%
Total:	204	100.00%

The study participants were equally distributed amongboth the groups, with each group comprising 102 participants.

Table-4: Distribution of study participants on the basis of Onset of action of mydriasis in Group-A (topical).

Onset of action	Frequency	Percentage
(10-15) minutes	38	37.25
(16-25) minutes	15	14.70
(26-30) minutes	44	43.13
(31-45) minutes	5	4.90
Total:	102	100.00

Among the study participants, in Group-A, it has been observed that, in 43.13% (majority) of the population, the onset of action of mydriasis was within 26 to 30 minutes of the topical drug administration; followed by 37.25% within 10 to 15 minutes; 14.7% within 16 to 25 minutes & only 4.9% of the participants had an onset of action within 31 to 45 minutes.

Table-5: Distribution of study participants on the basis of Onset of action of mydriasis in Group-B (intracameral).

Onset of action	Frequency	Percentage
(0-10) seconds	26	25.49
(11-20) seconds	53	51.96
(21-40) seconds	17	16.66
(40-60) seconds	6	5.88
Total:	102	100.00

Among the study participants, in Group-B, it has been observed that, in 51.96% (majority) of the population, the onset of action of mydriasis was within 11 to 20 seconds of the firstintracameral dose (0.2mL), in the operating table; followed by 25.49% within 0 to 10 seconds; 16.66% within 21 to 40 seconds; & 5.88% had an onset of action of within 40 to 60 seconds.

Table-6: Distribution of study participants on the basis of Pupil Size, measured at different time points during the surgery.

Pupil size	Mean/Standard deviation (mm.)		P-value
	Group-A	Group-B	
T-0	3.00+/-0.33	3.01+/-0.29	0.238
T-1	7.81+/-1.03	7.45+/-0.81	0.004
T-2	7.50+/-0.80	7.30+/-0.81	0.037
T-3	6.01+/-0.70	6.45+/-0.91	0.000

The pupil size was measured, in millimeter (mm.), using Castroviejo's caliper, in both the groups, at four time points during the surgery. A) **T-0**: Prior to drug administration; B) **T-1**: 30 minutes after topical drug administration (Group-A) & 60 seconds after intracameral injection (Group-B); C) **T-2**: Immediately prior to CCC (Continuous Curvilinear Capsulorhexis); D) **T-3**: After aspiration of cortical matter from the anterior chamber.

Among the study participants, it has been observed that, at time T-0, the mean dilatation of pupil, when compared between the two groups, was almost identical in both the groups. However, it was observed that the mean pupillary dilatation was larger in the topical group (Group-A) at times T-1 and T-2. But, after the aspiration of cortical matter from the anterior chamber (T-3), it was observed that mean pupillary dilatation was larger in the intracameral group (Group-B). Moreover, the time duration for which the pupil was larger during the surgery was found to be better in the intracameral group (Group-B) than the topical group (Group-A).

Table-7: Distribution of study participants on the basis of Systolic (SBP) & Diastolic Blood Pressure (DBP) at different time points during the surgery (Group-A).

SBP	Mean±Standard deviation (mmHg.)	P-value
T0	131.43 ±15.86	0.001
T1	145.75 ±17.28	0.001
T2	141.20 ±19.05	0.001
DBP		
T0	91.47 ±11.91	0.001
T1	90.40 ±14.36	0.001

T2	89.47 ±10.73	0.001

Among the study participants, in Group-A, it has been observed that, there was a rise in the mean SBP from T-0 to T-1; which again, decreased thereafter at T-2.However, it was within the permissible limit.

Whereas, a fall in the mean DBP was observed, starting from T-0 to T-2 (within permissible limit).

Table-8: Distribution of study participants on the basis of Systolic (SBP) & Diastolic Blood Pressure (DBP) at different time points during the surgery (Group-B).

SBP	Mean±Standard deviation (mmHg.)	P-value
T0	130.12 ±11.87	0.001
T1	133.40 ±17.60	0.001
T2	131.43 ±19.05	0.001
DBP		
T0	89.47 ±11.90	0.001
T1	88.33 ±14.36	0.001
T2	87.03 ±10.70	0.001

Among the study participants, in Group-B, it has been observed that, there was a rise in the mean SBP from T0 to T-1; which, again, decreased at T-2 (within permissible limit). Whereas, it was observed that there was a fall in the mean DBP from T-0 to T-2 (within permissible limit).

Table-9: Distribution of study participants on the basis of Pulse Rate (PR) at different time points during the surgery (Group-A).

PR	Mean±Standard deviation (bpm.)	P-value
T0	81.30 ±11.49	0.001
T1	79.26 ±10.52	0.001
T2	78.14 ±11.51	0.001

Among the study participants, in Group-A, it has been observed that there was a fall in the pulserate from T-0 to T-2; which was within the permissible limit.

Table-10: Distribution of study participants on the basis of Pulse Rate (PR) at different time points during the surgery (Group-B).

PR	Mean±Standard deviation (bpm.)	P-value
T0	77.27 ±10.49	0.001
T1	75.50 ±13.70	0.001
T2	75.87 ±12.35	0.001

Among the study participants, in Group-B, it has been observed that there was a fall in the pulserate towards the end of the surgery (within permissible limit).

DISCUSSION:

Achieving a rapid,adequate& steady mydriasis is a crucial aspect for anycataract surgery.The conventional approach to pupil dilation isusually by the instillation oftopicalmydriatic drops, prior to cataract surgery. However, due to its drawbacks, various other methods for pupil dilation have been tried. It hasbeen demonstrated that mydriatic & analgesic agents, administered intracamerally, can be used to achieve rapid, adequate & safe mydriasis; which can replace topical medications for the purpose of pupil dilation before cataract surgery. It has also been shown thatintracameral drugs are both safe & efficient.

In our study, we have employed two different methods for pupil dilation, priorto cataract surgery(phacoemulsification) &thereby, compared the safety & efficacy ofthese two techniques. The patients, aged 40 to 80 years, were chosen& were randomly split into two groups. Of these two groups, 102 patients receivedtopical mydriatic drops & 102 received intracameralmydriatic injection.Only one eye per patient was included & parameters such asonset of action of mydriasis, pupil size attained during various phases of the surgery,variation of blood pressure & pulse rate before, before, during & after surgery, were examined.

In our study, it was observed that, in Group-A,the largest number of study participants (35.29%) were between 60 to 70 years; while the least number of study participants (15.68%) were between40 to 50 years. However, in Group-

B,the largest number of study participants (50%) were between 40 to 50 years, while the least number of study participants (7.84%) were between 60 to 70 years. The study population in Group-A was composed primarily offemales (89.21%) &maleswere 10.78%. However, in Group-B, the study population consisted of 50.98% male participants & 49.01% femaleparticipants.

When the groups were compared, it was observed that, the topical group(Group-A) had a comparatively greater mean pupil dilation at 30 minutes after the start of topical drug administration (T-1), i.e.- (7.81+/-1.03) mm. & immediately prior to Continuous Curvilinear Capsulorhexis (T-2), i.e.- (7.50+/-0.80) mm.; as compared to (7.45+/-0.81)mm. &(7.30+/-0.81) mm., in Group-B, respectively. However, following the aspiration of corticalmatter from the anterior chamber (T-3), the mean pupil size was comparatively larger in theintracameral group (Group-B)i.e.- (6.45+/-0.91) mm. Moreover, thetimeduration forwhichthepupil was largerduringthesurgerywasfoundtobe better in the intracameral group (Group-B) than the topical group (Group-A).

It was observed, in the topical group (Group-A), that 43.13% of the study participantshad an onset of action of mydriasis within 26 to 30 minutes of topical drop administration; 37.25% within 10 to 15 minutes; 14.7% within 16 to 25 minutes; 4.9% within31 to 45 minutes. Whereas, in the intracameral group (Group-B), 51.96% of the studyparticipants had an onset of action within 11 to 20 seconds; 25.49% within 0 to 10 seconds; 16.66% within 21 to 40 seconds; 5.9% within 40 to 60 seconds.

Moreover, it was observed that the mean changes in the blood pressure & pulse rate, measured during various time points during the surgery, were within the permissible limit.

CONCLUSION:

It can be accepted that the administration of intracameralmydriatic provides a rapid, safe & adequatemydriasis throughout the cataract surgery, with lesser systemic side-effects; which makes it an effective alternative totopical medications. However,further research is always required upon its role in cataractsurgery. Nevertheless, intracameral administration of anaesthetic & mydriatic agents should, in fact, be promoted over the use of topical mydriatic,during cataract surgery.

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