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Efficacy and Safety of Intraoperative Intracameral Mydriatic injection in comparison with Preoperative topical mydriatics in cataract surgery: Randomized control trial

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Abstract:
Background*: Topical mydriatic drugs used for preoperative mydriasis in cataract surgery increased the risk of cardiovascular events and interfere the quality of visualization during surgery due to surface toxicity. With development of intracameral mydriatic agents it is shown to achieve fast onset of mydriasis and low systemic absorption with some disadvantages like corneal hyperemia, macular edema,keratitis, increased IOP,PCR and nervous system disorder.This study was conducted to detect the efficacy and safety of intracameral mydriatic injection compared to conventional topical mydriatics*.
Materials and Methods*:* **:** *A hospital based randomized control study was conducted in the Department of Ophthalmology, from May 2022 to June 2024 including 84 uncomplicated cataract patients attending Ophthalmology OPD satisfying all the inclusion criteria.*
Results*: it is found that the Mean pupil size is more in topical group vertically and horizontally (p value 0.30 and 0.25 respectively) after AC entry. Mean pupil size in both groups progressively reduced, just after nucleus extraction, before IOL implantation and before removing lid spectrum. On first postoperative day, there was no significant difference in distribution of corneal edema scores, AC inflammation scores, and in visual acuity between the two groups.*
Conclusion *The study findings shows the efficacy of mydriatic effects in term of sustainability despite, lesser pupil dilation in intracameral group. Also, There was no statistically significant differences between the distribution of corneal edema and AC inflammation and postoperative visual acuity between the groups.*
Key Word*: Intracameral; Mydriatic; topical Mydriasis; Pupil size.*

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I. Introduction

Cataract surgery is the most commonly undertaken surgical procedure performed worldwide.1 The demand for cataract surgery is increasing and will continue to increase. The introduction of small incision phacoemulsification led to substantial decrease in duration of surgery, the postoperative course and hospitalization. It is the most common, minimally invasive procedure done in an outpatient setting . During this procedure induction of pupil mydriasis and maintenance of an adequate degree of mydriasis throughout the procedure are critical for successful lens removal and implantation. Additionally good anaesthesia is essential for the performance of safe intraocular surgery creating a comfortable environment for the patient and surgeon. Insufficient mydriasis or pupil constriction can lead to several risks such as incomplete cortex removal, posterior capsule rupture, vitreous loss and dislocation of lens material and insufficient mydriasis is also discomfort for the surgeon as it makes instrument manoeuvring difficult. If mydriasis fails, surgeon might utilize rescue mydriatic therapies and procedures to redilate the pupils and maintain iris retraction and or control iris floppiness.The standard combination of two topical mydriatic drugs(tropicamide, cyclopentolate, phenylephrine) to achieve appropriate preoperative mydriasis presents increased risk of cardiovascular events that could possibly expose to overdose. A particular side effect of overdose is the ocular surface toxicity leading to toxic keratopathy.9 Intracameral injections were developed as an alternative to the conventional topical

Preoperative Mydriatics.It contains a combination of two mydriatics(tropicamide 0.02%, phenylephrine 0.31%) and one anaesthetic (lidocaine 1%).it is injected intracamerally under topical anaesthesia by the surgeon at the beginning of the surgery through side or main port. Due to localized specific therapy, it was shown to achieve fast onset of mydriasis and low systemic absorption and a good safety profile of ICMA(Intracameral Mydriatic Agents). The patients who had ICMA were more comfortable during surgery and spent less time overall in the preoperative and surgical room than those who received topical mydriatics.6 Though it has many advantages, certain disadvantages such as corneal hyperemia,macular edema ,keratitis, increased intraocular pressure posterior capsule rupture and nervous system disorders.4 The pupillary mydriasis achieved by ICMA 4 may also be less than the standard topical mydriatics.7 Since very limited number of studies concerning mydriasis and anaesthetic property were done on intracameral mydriasis comparing with topical mydriatics, hence this study was conducted to detect the efficacy and safety of intracameral mydriatic injection compared to conventional topical mydriatic.

II. Material And Methods

This randomized control study was carried out on patients of Department of Ophthalmology at Regional institute of medical sciences which is a tertiary care hospital in Imphal, Manipur from May 2022 to June 2024.The total patients attending OPD per month is around 2750 – 2770 A total of 84 adult subjects (both male and females) oof age 40 to 90 years were included in the study.

Study Design: Hospital based randomized control study
Study Location: This study was conducted in the department of Ophthalmology, Regional institute of medical sciences which is a tertiary care hospital in Imphal, Manipur. The total patients attending OPD per month is around 2750 – 2770, Among them are 60 – 90 cataract patients attending Monday and Thursday OPD. This hospital is located in west Imphal and receives referral from different health care centres in the state.
Study Duration: May 2022 to June 2024.
Sample size: 84 patients.

Sample size calculation: The sample size was calculated by the following formula N = (u + v)2 (s12 + s22) (m1 - m2)2 U = study power at 80% = 0.84 V = significance level 95% = 1.96 M1 = pupil size just before IOL implantation in topical group compared to baseline = 5.5 3 S1 = standard deviation of topical group compared to baseline = 1.2 M2 = pupil size just before IOL implantation in intracameral group as compared to baseline = 6.2 3 S2 = standard deviation in intracameral group as compared to baseline = 1.3 Applying the values N = 39 N with 10% attrition rate Hence the sample size, N = 42 in each group.

Subjects & selection method: All the uncomplicated cataract patients who attended ophthalmology OPD Regional institute of medical sciences hospital who fulfilled the inclusion and exclusion criteria was enrolled in the study. Once recruited, the patients was randomized into two equal groups (n = 42) as Topical and Intracameral groups by computerized block randomization (block size 4). The computerized random numbers was generated by a person who is not involved in the study. 23 it was a Single blinded study. The patients were not aware of which group they belong.

Inclusion criteria:
1. Uncomplicated cataract patients eligible for surgery between 40 to 90 years
2. Preoperative Pupils atleast 6mm.

Exclusion criteria:
1. Uveitis
2. Intake of alpha blockers
3. Use of topical or systemic NSAIDS/prostaglandins/miotics
4. Presence of corneal opacities,pupillary deformities 22
5. History of surgery in the same eye
6. Congenital cataract
7. History of ocular trauma

Procedure methodology

All the subjects underwent comprehensive ophthalmic examinations including Refraction, Slit lamp Biomicroscopy, Intraocular pressure, Dilated fundoscopy, A-Scan Ultrasonography. Best corrected visual acuity (BCVA) was assessed using Snellens visual acuity chart and the patient underwent slit lamp examination to assess the preoperative pupillary dilatation and to evaluate the cataract grading. Patients allocated to

Intracameral group were not administered any topical dilating drops preoperatively. Mydriasis was achieved intraoperatively by the surgeon by injection (Tropicamide 0.02%, Phenylephrine 0.31%, Lidocaine 1%) intracamerally. Pupil sizes were measured serially at different junctures (before block, 30sec after Intracameral Instillation of Mydriatic, just after nucleus extraction, just before IOL implantation, just before removing lid speculum) during Manual Small Incison cataract surgery . Patients allocated to Topical group underwent pupillary dilatation on the day of surgery with preoperative topical eye drops using a standard regimen (tropicamide 0.8% and phenylephrine 5%) at 15 mins interval for 1 hr before surgery. Pupil sizes were measured serially at different junctures(before block,1min after AC entry in topical , just after nucleus extraction, just before IOL implantation, just before removing lid speculum) during Manual Small Incison surgery. First postoperative day Visual Acuity, Corneal Edema scores and Anterior Chamber Inflammation scores were noted in all the patients in both Intervention and Control groups

Statistical analysis

Data collected in the proforma were checked for consistency and completeness. They was entered in the IBM SPSS version 21.0 software(IBM corp . Armonk .NY,USA) for analysis. Descriptive statististics like mean, percentage and standard deviation was used to represent age , sex. The pupil size was analysed by Chi Square test. Postoperative Visual Acuity , Corneal Edema and Anterior Chamber inflammation scores was compared and statistically analysed using the paired t- test and independent t- test. The level $P < 0.05$ was considered as the cutoff value or significance.

III. Result

Total 84 cases of uncomplicated cataract patients enrolled in the study. All participants were enrolled through randomization process and 42 each assigned in interventional group (Intracameral group) and other 42 were assigned in comparative group (Topical). The mean age of the study participant 69.60 ± 8.04 years ranges from 51 to 88 years.

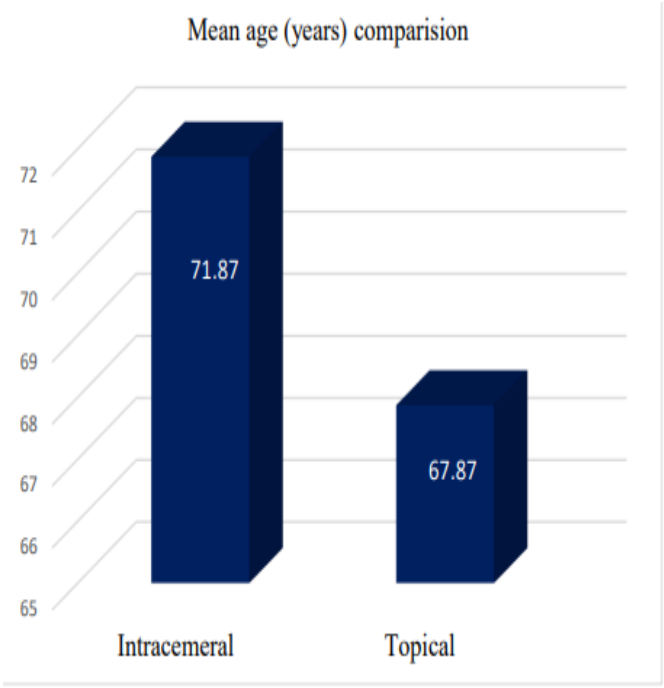

Figure 1: Mean age comparison (N=42 each group)

Figure 1 above table 1 depicted that mean age in intracameral group was slightly higher (71.87 ± 7.53) than topical group (67.87 ± 8.75); however, the difference was statistically not significant (p value .191).

Table 1a: Mean age comparison in between the study group (N=84)

Variable	Study group (mean SD)		Mean difference	P value
	Intracameral	Topical		
Age (years)	71.87 ± 7.53	67.87 ± 8.75	4.00	0.191

Table 1b: Age group comparison (N=84)

Age group	study group n(%) Intracameral	Topical	P value
<60 years	7 (50.0)	7 (50.0)	0.179
61-70 years	13 (36.1)	23 (63.9)	
>70 years	20 (58.8)	14 (41.2)	

Figure 2: Age group (%) comparison (N=84)

The age group distribution in between the study group was not difference (p value .179) across the age. Aged between 61-70 years was higher among topical group (63.9% vs 36.1%) and above 70 years aged was found in intracameral group (58.8% vs 41.2%).

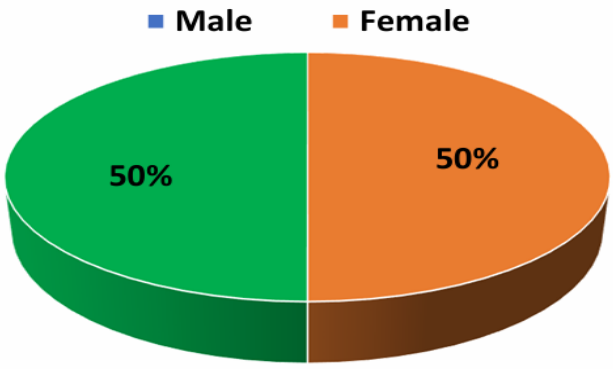

Figure 3: Gender Distribution (N=84)

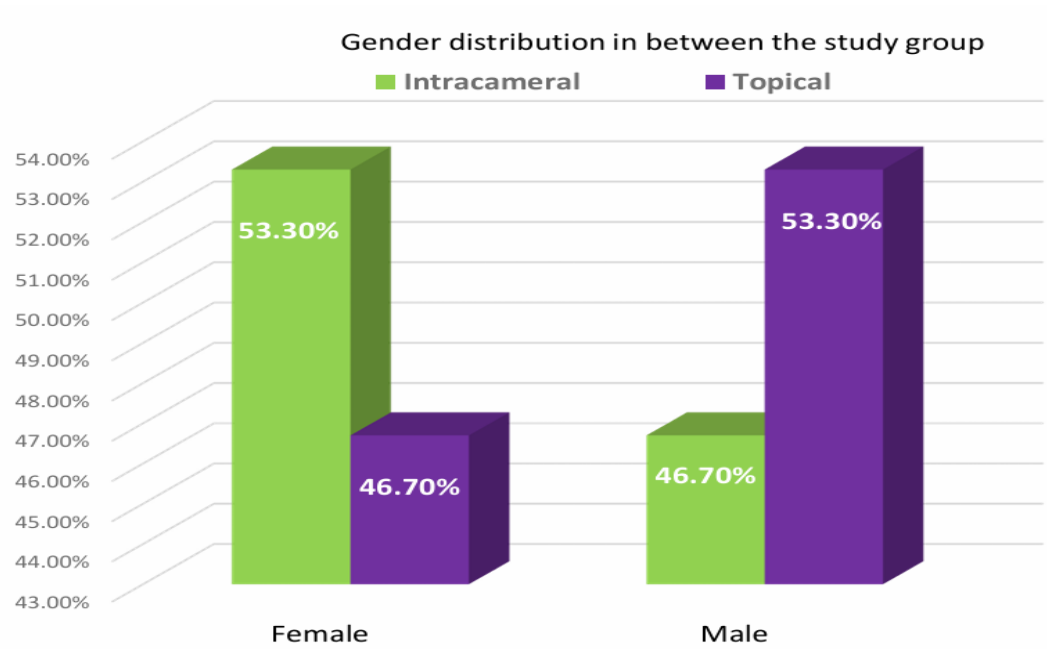

Figure 4: Gender distribution in between the study group (N=84)

Above figure 3 & 4 shows that the gender distribution of the participants in between the study group. Male participants were high in topical group (53.3%) and female were more in intracameral group (53.3%).

Table 2: Comparison of co-morbidities among the study group (N=84)

Co-morbidities N (%)	Intracameral group (n=42)	Topical group (n=42)	Total / p value
Absent	16 (47%)	18 (53%)	34 (40.5%)
Present: COPD Type 2 DM Hypertension	21(42%) 1 (50.0) 11 (52.3%) 9 (33.3%)	29 (58%) 1 (50.0) 10 (47.7%) 18 (66.7%)	50 (59.5%) ---- .422 .069

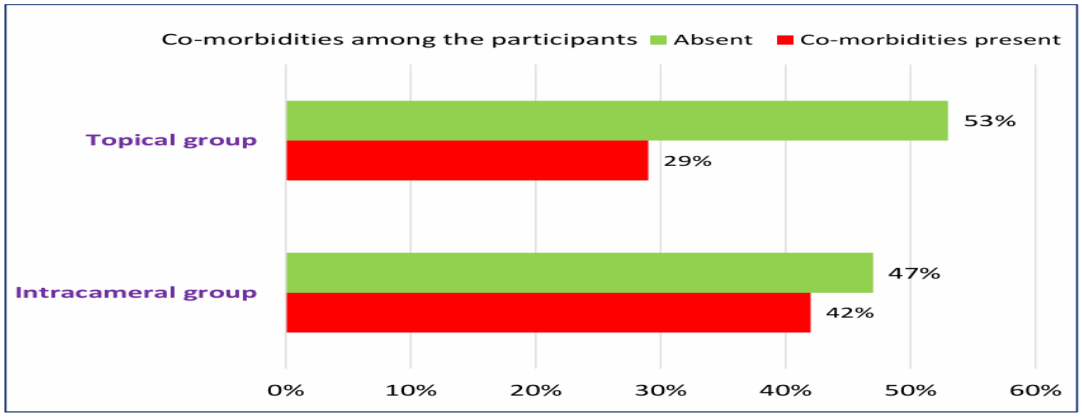

Figure 5: Comparison of co-morbidities among the study group (N=84)

In table 2 and figure 5 demonstrated that about 60% of the participants are having comorbidities. Such comorbidities – hypertension, type 2 diabetes mellitus are more common among topical group (66.7% and 47.7% respectively); however, this difference is not associated with study group (p value .422 and .069 respectively).

Table 3: Eye side involvement in the study (N=84)

Eye Side	Intracameral group (n=42)	Topical group (n=42)	Total
Right	19 (45.2%)	20 (47.6%)	39 (46.4%)
Left	23 (54.8%)	22 (52.4%)	45 (53.6%)

In this study, left eye involvement is more (53.6%) than right eye (46.4%) and the distribution in between the study group also not much difference (p value .827).

Table 4: Comparison of pupil size in mm before surgery (N=84)

Pupil size before surgery	Intracameral* (n=42)	Topical (n=42)	Mean differences	P value
Vertical	2.70 ± 0.45	8.73 ± 0.41	-6.03	0.000
Horizontal	2.70 ± 0.45	8.63 ± 0.44	-5.93	0.000

*Preoperative dilatation was not done in study group 0.000
In above table 4, it is showing that there was significant difference of pupil size in both vertically and horizontally (mean difference of 6.03 and 5.93) among the study group with a p value of 0.000.

Table 5: Comparison of pupil size in mm after 1 minute of AC entry in topical and 30 sec after Intracameral injection in intracameral group (N=84)

after 1 minute in topical and 30 sec in intracameral	Intracameral (n=42)	Topical (n=42)	Mean differences	P value
Vertically	8.13 ± 0.66	8.66 ± 0.40	-0.53	0.30
Horizontally	8.20 ± 0.49	8.60 ± 0.43	-0.40	0.25

In table, showing that pupil size is more dilated in topical group vertically and horizontally (p value 0.30 and 0.25 respectively).

Table 6: Comparison of pupil size in mm just after nucleus extraction (N=84)

Pupil size after nucleus extraction	Intracameral (n=42)	Topical (n=42)	Mean differences	P value
Vertically	7.83 ± 0.64	8.40 ± 0.43	-0.56	0.91
Horizontally	7.80 ± 0.64	8.30 ± 0.45	-0.50	0.21

Table 7: Comparison of pupil size in mm before IOL implant (N=84)

Pupil size before IOL implant	Intracameral (n=42)	Topical (n=42)	Mean differences	P value
Vertically	7.73 ± 0.65	8.30 ± 0.45	-.56	.14
Horizontally	7.73 ± 0.65	8.40 ± 0.50	-.66	.42

Table 8: Comparison of pupil size in mm before removing lid spectrum (N=84)

Pupil size before removing lid spectrum	Intracameral (n=42)	Topical (n=42)	Mean differences	P value
Vertically	7.73 ± 0.65	8.30 ± 0.45	-.56	.11
Horizontally	7.73 ± 0.65	8.40 ± 0.50	-.66	.48

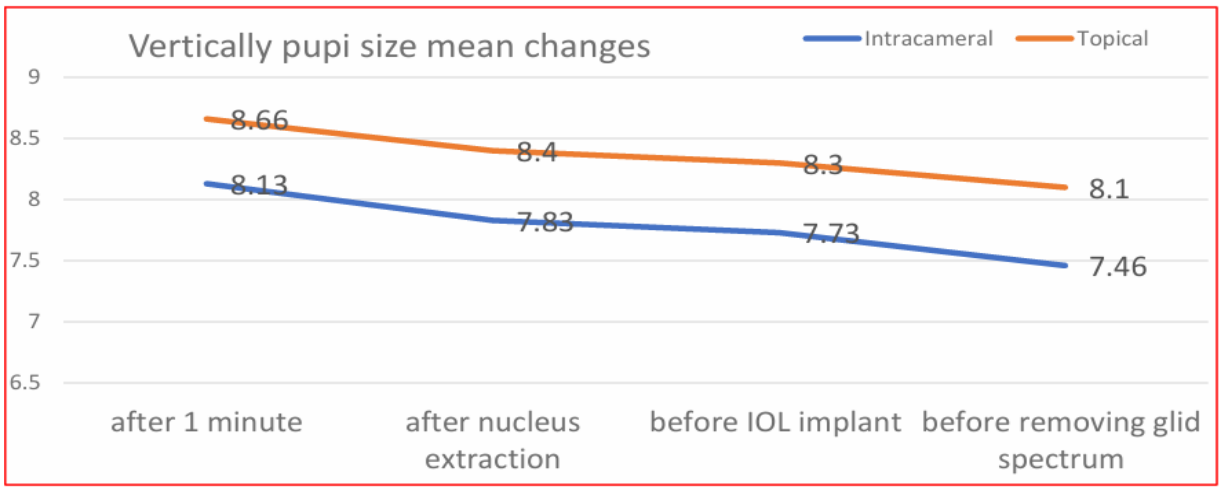

Figure 6: Vertical pupil size mean changes during surgery (N=84)

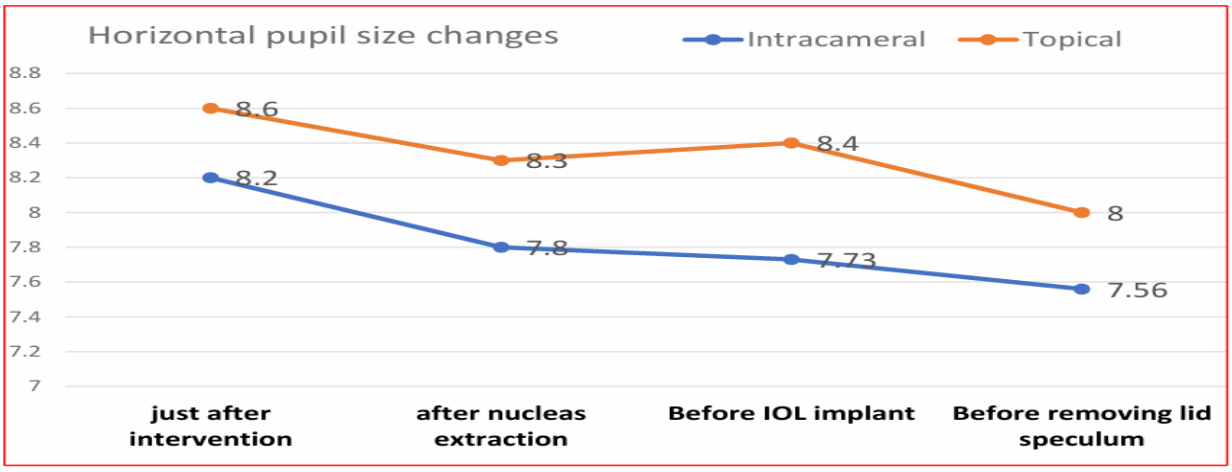

Figure 7: Horizontal pupil size mean changes during surgery

In the present study findings from table 6 to 8 and figure 6 and 7, shows that there was no significant changes in pupil dilation with intracameral group compared to topical group.

Table 9: Visual acuity preoperative comparison (median) in between intergroup

Variable	Intracameral group (n=42)	Topical group (n=42)
Visual acuity	6/60 = 11 6/36 = 11 6/12 = 4 6/24 = 3 1/60 = 3	6/36 = 13 6/60 =10 6/24 = 5 6/12 = 4 3/60 = 4

Above table 9 shows that visual acuity problem in both study group almost equally. 6/60 was in intracameral group and 6/36 was in topical group before intervention.

Table 10: Visual acuity changes post operatively in between intergroup

Variable	Intracameral group (n=42)	Topical group (n=42)
Visual acuity	6/12 = 10 6/9 = 8 6/6 = 7 6/24 = 7 6/18 = 3	6/12 = 16 6/9 = 8 6/18 = 8 6/6 = 7 6/12 = 2

After the surgery, visual acuity was improved in both groups. 6/12 (n=10) was common in intracameral group and 6/12 visual acuity in topical group was 16 in number.

Table 11: Visual acuity intragroup changes post operatively (median) (N=84)

Variable	Intracameral group (n=42)	Intracameral group (n=42)	Topical group (n=42)	Topical group (n=42)
	Before	After	Before	After
Visual acuity (common)	6/60 = 11 6/36 = 11	6/12 = 10 6/9 = 9 6/6 = 7	6/36 = 13 6/60 =10	6/12 = 12 6/6 =8 6/9 = 8

Above table 11 clearly depicted that before and after surgery effects in between the study group. Visual acuity was improved in both group.

Table 12: Distribution of corneal edema among the study group (N=84)

Post operatively complications N (%)	Intracameral group (n=42)	Topical group (n=42)	P value
Corneal edema	2 (33.3)	4 (66.7)	.396
Edema absent	40 (51.3)	38 (48.7)	

As efficacy of the interventional drug, the corneal edema development as a side effect was much lesser in intracameral group (33.3%) than topical group (66.7%); however, there was no significant association (p value .396) (table 12 and figure 8).

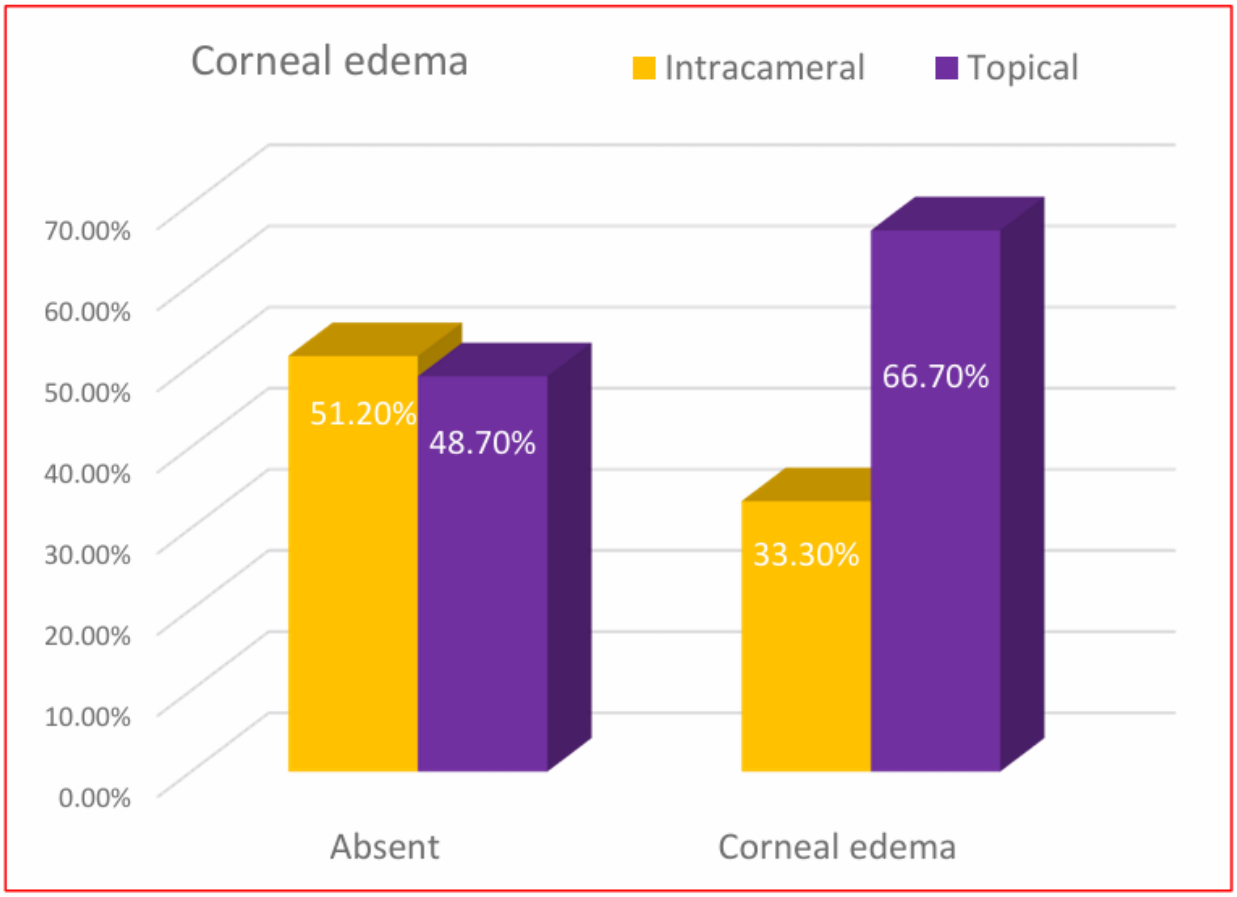

Figure 8: Comparison of corneal edema (side effects) in between the group

Table 13: Comparison of corneal edema grades postoperative side effects in between the study group (N=78)

Corneal edema grades	Intracameral group N (%)	Topical group N (%)	P value
Grade 1, mild (Descemet folds only)	17 (56.7)	13 (43.3)	.292
Grade 2, moderate (stromal edema with Descemet folds)	23 (48.9)	24 (51.1)	
Grade 3, severe (stromal and epithelial edema)	0 (0.0)	1 (100.0)	

In above table, corneal edema was mostly observed in topical group moreover, higher the edema grade was seen in topical group only. There was only 1 grade 3, severe form (stromal and epithelial edema) corneal edema developed during the study period. Mild form edema was higher in intracameral group (56.7%) than topical group (43.3%). There was no significant association found (p value .292).

Table 14: Comparison of anterior chamber inflammation score / grades postoperative side effects in between the study group (N=78)

Anterior chamber inflammation score / grades	Intracameral group N (%)	Topical group N (%)	P value
Grade 1 (6–15 cells)	6 (42.9)	8 (57.1)	.203
Grade 2 (16–25 cells)	26 (60.5)	17 (39.5)	
Grade 3 (26–50 cells)	6 (33.3)	12 (66.7)	
Grade 4 (>50 cells)	1 (33.3)	2 (66.7)	

Above table depicted that higher grades or scores of anterior chamber inflammation were more among topical study group (grade 3 and 4: 66.7% and 66.7%); however, there was no significant association between grades of anterior chamber inflammation score and study group (p value .203).

IV. DISCUSSION

The present study was initiated to determine the efficacy and safety of intracameral mydriatic Injection Tropicamide 0.02% + Phenylephrine 0.31% + Lidocaine 1%, as compared to preoperative topical mydriatics (tropicamide 0.8%, phenylephrine 5%) in different cataract surgery. The findings showed that pupil size was more in topical group than intracameral group during the surgery time both vertically and horizontally. However, Mydriatic effect in terms dilation of pupil is not much different in between the group.

In a study by Suresha AR et al27 shown that an increase of 0.7 ± 0.283 mm from baseline pupillary size of 3.7 ± 0.962 mm was noted after peribulbar block and the value of 7.35 ± 1.205 mm was obtained following intracameral injection of a mydriatic solution, which slowly decreased to 6.03 ± 1.327 mm after Irrigation and aspiration of cortical matter and 5.7 ± 1.212 mm after IOL implantation to reach 5.53 ± 1.171 mm at the end of the surgery. The present study also in same line where pupillary size was changes from 8.2 mm to 7.56 mm at the end of surgery.

Similarly, Samarai V et al28, also demonstrated same findings in their case control study that Pupil size increased in both case and control groups significantly (P value< .0001). The least-square mean difference change from baseline between the study drug and ketorolac was 0.7 ± 0.1 mm (95% CI, 0.5-0.9; P < .0001). An analysis of mean pupil diameter changes by minute showed that the study drug-maintained mydriasis better than both ketorolac and the phenylephrine by the fourth minute of the procedure (both P < .001). This finding is contradictory to our study findings.

In many previous literatures, like Gupta SK et al21, Muhtaseb M et al30, Mehta S et al31, Martin RG et al32, Deeks ED33, significant difference was observed in pupil size in between the intracameral and topical solution in different MICS or phacoemulsification where dilation was more in intracameral group.

One of the Indian studies by Kaur S et al24 demonstrated that with intracameral injection there was sudden significant changes for pupil size.

In one In a RCT study34 to assess the efficacy and safety of intracameral mydriatic solution, was compared to preoperative topical mydriatics, in manual small incision cataract surgery (MSICS) and to assess the sustainability of intracameral mydriasis in by monitoring pupil size at specific stages during the surgery. In their study it was 41 observed that Mean pupil size just before peribulbar block was 7.3 mm in topical group and 3.3 mm and in intracameral group (P < 0.001). pupil diameter in intracameral group increased to 7.3 mm 30 s after intracameral Mydriatic Injection. Mean pupil size in both groups reduced, reaching 5.5 mm (topical) and 6.2 mm (intracameral) before IOL implantation (P = 0.001), and measured 5.1 mm and 5.5 mm at the end of surgery (P = 0.048).34 But our study shows lower pupillary size dilation in intracameral group.

The present study also found that visual acuity was improved better in intracameral group than topical group in MICS – cataract surgeries; however, the improvement was comparable in both groups. As assessment

of efficacy of the study drug, post operative complications were lesser in proportion in intracameral group than topical group. Severe form of Corneal oedema grades also comparatively lesser. Similarly, higher grades anterior chamber inflammatory also lesser in intracameral group; however, it was comparable in both groups.

Similarly finding was observed in a study by Katti V et al34, on first postoperative day, there was no significant difference in distribution of corneal oedema scores, AC inflammation scores, and in median logMAR visual acuity between the groups.

Sukhija J et al35, Gowda A et al36, Morgado G et al37, Bielory BP et al38, and Labetoulle M et al2 also found similar findings in their studies where the post operative side effects were comparable with study groups.

In a study by Labetoulle M et al4 in Europe and Algeria shows ICMA is effective and was safely used in patients with controlled diabetes, with advantages compared to a topical regimen including reduced systemic risk, better corneal integrity and reduced risk of ocular complications.

Lay Suan AL et al11 shows that 42 side effects are comparable in between the group and visual acuity also improved comparatively. There was no significant difference in mean pupil dilation between the intracameral group (4.86 mm ± 0.74 [SD]) and the topical group (4.88 ± 0.91 mm) (P = .86). However, the mean pupil size before capsulorhexis in the topical group (7.23 ± 1.08 mm) was significantly larger than in the intracameral group (6.40 ± 0.80 mm) (P = .01). The pupils in the intracameral group continued to dilate during surgery (0.44 ± 0.62 mm), while those in the topical group constricted (-0.41 ± 1.04 mm) (P < .001).

Dereń-Szumełda JK et al39 found significant findings in visual acuity improvement and better post operative outcome among the intracameral group.

Ben Hadj Salah and colleague40 found that There was no statistical differences between series in the change in corrected distance visual acuity from preoperatively to 1 month postoperatively and in complications (P > .05, all comparisons) and this finding is similar to the present study.

Schulz, C.B et al6 also found same findings that postoperative Visual acuity was comparable between groups (0.09±0.16 vs 0.08±0.15; p=0.59). Pupil size in group 2 was 7.0±1.0 mm before capsulorhexis and 6.5±0.29 mm just after cortical aspiration, with a smaller pupil in patients on Alpha-antagonists (4.7±1.1 mm; p=0.004) at this later point of time. Similar impact also seen in a study by Simmon R et al26 where visual acuity was comparable.

Souki S et al23 found the difference between Fydrane group and control group for the change from baseline at day 1 in corneal and conjunctival surface staining was not significant. For Fydrane, postoperative epithelial were fewer at day 1 (P < .005), folliculopapillary reaction was less frequent (P < .05), some ocular symptoms were less frequent and milder (P < .05), length of procedure was shorter (P < .001), and patient and investigator satisfaction were better (P < .05). There were few AEs in both groups. 43

Optimal mydriasis and anaesthesia are the important factors influencing the safety of cataract surgery and the patient's comfort in the perioperative period. Due to its faster onset of anaesthesia, better consistency, effectiveness, and patient compliance as well as faster post-operative patient rehabilitation, topical anaesthesia is gradually replacing the use of the peribulbar block.14,19,25

However, patients do experience some intraoperative pain, especially during iris tissue contact or manipulation. Intracameral anaesthesia is a newer option which provides dual and simultaneous benefit of mydriasis and analgesia in modern cataract surgery.

However, an intracameral combination of a mydriatic and anaesthetic is not that effective in providing mydriasis as compared to topical as seen in our study. [44]

LIMITATION

Small sample size involved in the present study was on of the drawback of the study. Co-variates or confounders may also play a role for not significant difference in different findings of the present study which needs to be controlled to make study robust. Follow up can be made to see the long term efficacy of the study drug.

V. CONCLUSION

The present study findings show that the efficacy of mydriatic effects in terms of sustainability has no significant difference between the study groups. However, there is lesser pupil dilation in the Intracameral group. • Though the proportion of postoperative complications was lesser in the intracameral group, there was no statistically significant difference between the distribution of corneal oedema scores and AC inflammation scores among the two groups. • There was also no statistically significant difference in postoperative visual acuity between the two groups.

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