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A Comparative Analysis Of Pain In Phacoemulsification Cataract Surgery With Proparacaine Hydrochloride (0.5%) Vs Combined Topical Proparacaine - Intracameral Phenylephrine(0.31%),Tropicamide (0.02%) And Lidocaine (1%) With Efficacy Of Icam In Achieving Optimum Intraoperative Mydriasis

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Abstract

This study supports the adoption of a combined anesthesia regimen using Proparacaine Hydrochloride (0.5%) and intracameral anesthesia in phacoemulsification cataract. Surgery and usage of sole intracameral mydriatic anesthetic for pupillary dilation in certain cases for achieving dilation prior to cataract surgery.

Keywords: Phacoemuslification , topical anaesthesia , intracameral anaesthetic and mydriatic

Introduction

The surgical method currently used to treat maximum cases of senile cataract is phacoemulsification under local anaethesia3. An acceptable anaesthesia modality for a cataract surgery implies the correct choice of anaesthetic agent, combined with a compatible clinical technique, ensuring patient comfort both during and post surgery.Retrobulbar or peribulbar anaesthesia or topical anaesthesia (alone or with intracameral anaesthesia) are commonly used for local anaesthesia

Pupil dilation (i.e. mydriasis) can be achieved by various means, with a standard regimen being topical phenylephrine plus tropicamide or cyclopentolate9. Intracameral mydriatic and anaesthetic are efficient and safe method for inducing and maintaining intraoperative mydriasis and analgesia, leading to increased patient comfort (especially during IOL implantation) and surgeon satisfaction10. Tropicamide 0.02% / phenylephrine 0.31% / lidocaine 1% injectable solution is the first fixed-dose mydriatic/anaesthetic combination approved for intracameral use in adults undergoing cataract surgery17. The visual analogue scale18 has a high reliability for the assessment of acute pain. So the visual analogue scale was used to assess the pain in this study.

When using a VAS to assess pain, subjects were asked to indicate intensity by marking a (usually) 100-mm-long horizontal line that is labelled “no pain” at one end and “worst pain possible” at the other end.

Aims And Objectives

1. To study the anaesthetic efficacy of topical 0.5% proparacaine hydrochloride versus combined topical proparacaine hydrochloride (0.5%)- intracameral phenylephrine (0.31%), tropicamide (0.02%) and lidocaine (1%) during phacoemulsification surgery.
2. To study the efficacy of Intracameral Anaesthetic Mydriatic (ICAM) in achieving optimum intraoperative mydriasis during phaco-emulsification surgery.

Material And Methods

This Prospective interventional comparative study was conducted in Department of Ophthalmology at a tertiary eye care hospital

Statistical Analysis

The collected data was entered in Microsoft Excel and then was analysed and statistically evaluated using SPSS-25 version. Normality of each variable was assessed by using the Kolmogorov- Simirnov test and Shapiro-Wilk test. Quantitative data was expressed by mean, standard deviation or median with interquartile range and depends on normal distribution, difference between two means was tested by student t test or Mann Whitney U test while for pre-post comparison paired t test or Wilcoxon signed rank test was used. (remove) Qualitative data was expressed in percentage and difference between the proportions were tested by chi square test and Z test of proportion test. 'P' value less than 0.05 was considered statistically significant.

Inclusion Criteria:

1. Age <65 years, Co-operative patients >65 years of age
2. Patients following verbal commands
3. Documented pupil dilation >6mm

Exclusion Criteria:

1. Uncooperative patients in any age groups
2. Rigid, Non dilating pupil
3. Grade 4 cataract, mature cataract, complicated cataract
4. Pre-existing zonular weakness

This prospective interventional comparative study included patients diagnosed with cataract who are getting admitted and consented to undergo cataract surgery. A total of 46 patients were enrolled in this study. Patients who were less than 65 years of age or cooperative patients who were more than 65 years of age, and patients that could follow verbal commands were included in this study.

The patients were randomly divided in 2 groups; Group A, Group B.

Group A (n=23) : Patients undergoing phacoemulsification cataract surgery topical anaesthesia with proparacaine hydrochloride (0.5%) only.

Group B (n=23) : Patients undergoing phacoemulsification cataract surgery under topical proparacaine hydrochloride (0.5) - along with intracameral phenylephrine (0.31%), tropicamide (0.02%) and lidocaine (1%)

Patients in both the groups underwent a thorough ophthalmological examination which included:

Patients enrolled in Group A were administered one drop of topical mydriatic agent (tropicamide 0.8% with phenylephrine 5%) in the eye to be operated, starting 1 hour before surgery and instilled 15 min apart, as per the traditional protocol and one drop of topical anaesthesia (proparacaine hydrochloride 0.5%) at 5 min interval, started 10 min before surgery.

Patients in Group B did not receive any topical mydriatic agent preoperatively. All the patients received one drop of topical anaethesia (proparacaine hydrochloride 0.5%) at 5 min interval, started 10 min before surgery. Intraoperatively all patients received ICAM injection for the dilation of pupil before commencement of the rest of the surgery.

One surgeon performed all surgeries. Same technique of surgery was used for patients in both the groups.

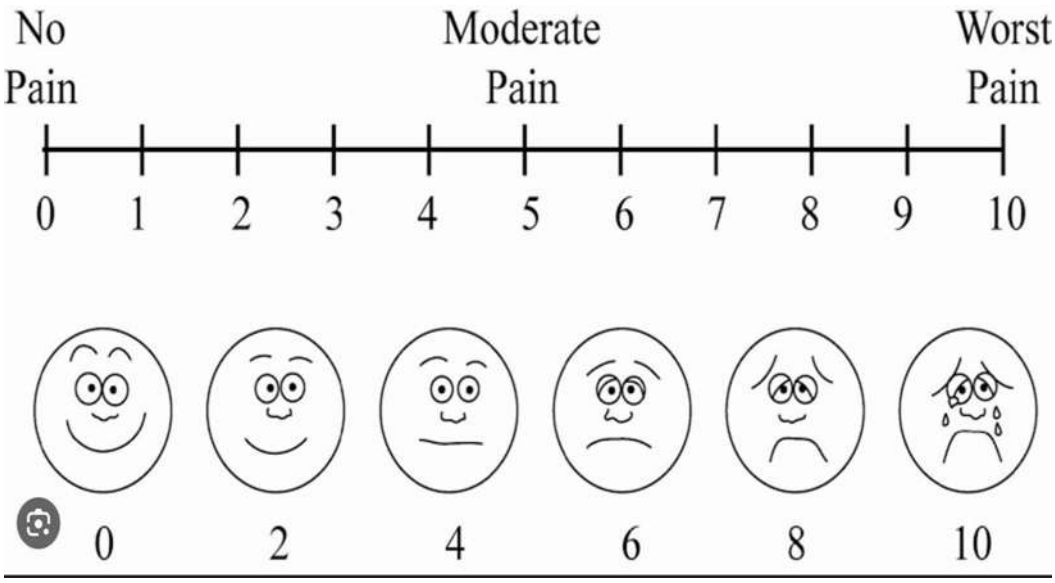
A universal eye speculum was used in all cases. Patients were instructed to fixate on the microscope light during surgery. 2 side port incisions were created on the appropriate side to stabilize the globe. ICAM injection was injected into the anterior chamber at this stage in patients from Group B. In patients from Group B, the pupil diameter of the eye to be operated on was measured by the operating surgeon under the microscope using a surgical Castrovejo calipers.

A 2.8 mm clear corneal temporal incision was performed through, which viscoelastic (2% Hydroxypropyl methyl cellulose, Appavisc) was injected. A 5.5 mm wide capsulorhexis was created using cystitome made with 26G needle. Complete cortical cleaving hydrodissection was performed by injecting a balanced salt solution between the lens capsule and the cortex with a 27-gauge cannula. The nucleus was divided using a direct chop technique. Cortical cleanup was performed with the irrigation/aspiration probe. A single piece foldable hydrophilic intraocular lens was implanted in the bag. The viscoelastic material was removed from the capsular bag and from the anterior chamber. Stromal hydration of the side port and main incision was performed. No sutures were required in any case. No

Volume 8, Issue 6; November-December 2025; Page No 624-633

complications occurred and no additional anaestheshetic or mydriatic was required in any case.

Pain assessment After 10 minutes of completion of surgery, each patient was shown a Visual Analogue Scale with numeric and descriptive ratings from 0 (no pain) to 10 (severe pain). Patients were asked to use this 10-point scale to rate the level of pain felt during the operation. In addition, any verbal expression of pain that patients made during the operation (During insertion of speculum, During Phacoemulsification, During IOL insertion) was recorded. Patients were asked to inform the surgeon if they experienced any pain at any point of the surgery. If so, additional anesthesia was given. Any ocular motility during the time of surgery, surgical complications and postoperative use of analgesics were recorded.



Observation & Results

Table 1 : Cataract Grading

Cataract Grading	Group A (n=23)		Group B (n=23)		Z test of proportion	P value	Chi square test	P value
	Number	Percent	Number	Percent				
NS1	9	39.1	11	47.8	0.59	0.55		
NS2	12	52.2	11	47.8	0.29	0.77	**1.91**	**0.59**
NS3	2	8.7	1	4.3	0.59	0 .54		
Total	**23**	**100.00**	**23**	**100.00**				

Volume 8, Issue 6; November-December 2025; Page No 624-633

Chi square test	**6.87**	**8.69**
P value	**0.032***	**0.013***

*Statistically significant at p<0.05

Table 1 shows cataract grading. In Group A, 39.1% patients had a grading of NS1, 52.2% had NS2 grading, and 8.7% had NS3 grading. In Group B 47.8% patients had a grading of NS1, 47.8% had NS2 grading and 4.3% had NS3 grading

Graph 1 summarises the intraoperative pain felt by patients at 3 stages, classified into no pain, mild pain, and moderate pain. In Group A no patient felt any intraoperative pain at speculum insertion, 19 patients felt no pain, 1 patient felt mild pain (4.3%) and 3 patients (13%) felt moderate pain at IOL insertion. 19 patients felt no pain, 1 patient (4.3%) felt mild pain, 3 patients (13%) felt moderate pain At phacoemulsification.

In Group B no patient felt pain at speculum insertion, no patient felt pain at IOL insertion. 21 patients (91.3%) felt no pain, 1 patient felt mild pain (4.3%) and 1 patient felt moderate pain (4.3%) At Phacoemulsification. This is statistically significant at p<0.05

Graph 1: Intraoperative Pain

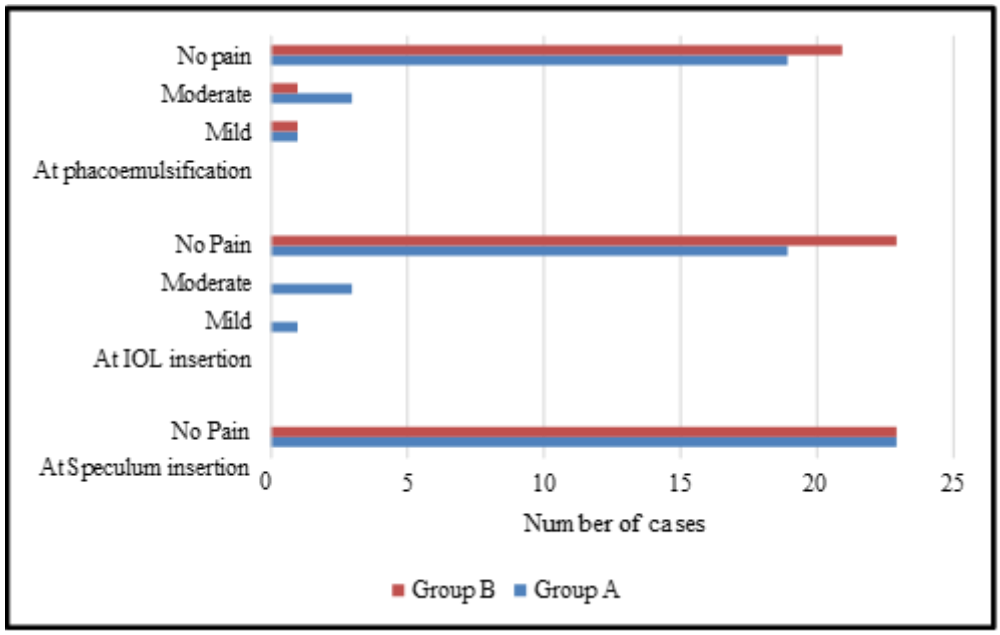


TABLE 2 : Overall Intraoperative Pain

Intra- operative Pain	Group A (n=23)		Group B (n=23)	
	Number	**Percent**	**Number**	**Percent**
No Pain	16	69.6	21	91.3
Mild	2	8.7	1	4.3

Volume 8, Issue 6; November-December 2025; Page No 624-633

Moderate	5	21.7	1	4.3
Chi Square Test	**14.17**		**34.7**	
p-value	**0.001***		**0.00***	

Table 3 : Post Operative Pain

Post-operative Pain	**Group A (n=23)**		**Group B (n=23)**	
	Number	**Percent**	**Number**	**Percent**
No Pain	19	82.6	23	100.0
Mild	4	17.4	--	
Moderate	**0**	**0**	-	-
Chi Square test	**14.17**		**--**	
p-value	**0.001***			

*Statistically significant at p<0.05

Table 3 summarises the postoperative pain that was felt by patients 10 minutes after completion of surgery. In Group A out of 23 patients 17.4% (4) patients felt mild postoperative pain and 82.6% (19) patients felt no pain. In Group B 100% patients felt no postoperative pain.

Table 4 : Mydriasis

Mydriasis	**Preoperative**		**Post Operative**		**Z test of proportion**	**P value**	
	Number	**Percent**	**Number**	**Percent**			
Optimum	23	100	16	69.6	0.28	0.004*	
Sub optimum	-	-	7	30.4	-	-	
Total	**23**	100.00	**23**	100.00			
Chi square test	-		3.52				
P value	-		0.06				

Volume 8, Issue 6; November-December 2025; Page No 624-633

*Statistically significant at p<0.05

Table 4 summarises the number of patients that achieved optimum intraoperative mydriasis (>6mm) after being subjected to ICAM. Our study included patients who had a preoperative documented pupil diameter of >6mm. Out of 23 patients 16 patients achieved optimum mydriasis, and 7 patients achieved suboptimum mydriasis after administration of ICAM.

TABLE 5: This table summarises the comparison between the Grade of Cataract and the overall intraoperative and post operative pain in GROUP A

		Over all intra-operative pain			Over all post-operative pain		
		No pain	**Mild**	**Moderate**	**No pain**	**Mild**	**Moderate**
Cataract Grading	**1**	9	0	0	9	0	0
	2	6	2	4	9	3	0
	3	1	0	1	1	1	0
Chi square Test		7.23			3.85		
p- value		0.12			0.14		

Table 5 encapsulates the comparison between the grade of cataract with intraoperative and postoperative pain in Group A. Patients with NS1grade cataract experienced no pain intraoperatively or postoperatively. 2 patients with NS2 grade cataract felt mild intraoperative and 3 patients with NS2 grade cataract felt mild postoperative pain. 1 patient with NS3 grade cataract felt moderate intraoperative pain and 1patient with NS3 grade cataract felt mild postoperative pain.

TABLE 5 : This table summarises the comparison between the Grade of Cataract and the overall intraoperative and post operative pain in GROUP B

		Over all intra-operative pain			Over all post-operative pain		
		No pain	**Mild**	**Moderate**	**No pain**	**Mild**	**Moderate**
Cataract Grading	**1**	11	0	0	11	0	0
	2	10	1	0	11	0	0
	3	0	0	1	1	0	0
Chi square test		25.97			-		
p- value		0.00			-		

Table 5 encapsulates the comparison between the grade of cataract with intraoperative and postoperative pain in Group B. Patients with NS1 grade cataract experienced no pain intraoperatively or

Volume 8, Issue 6; November-December 2025; Page No 624-633

postoperatively. 1 patient with NS2 grade cataract experienced mild intraoperative pain. 1 patient with NS3 grade cataract experienced moderate intraoperative pain.

Discussion

The findings indicate a notable difference in cataract severity between the two groups. Group A had a higher proportion of patients with more advanced cataract grading (NS2 and NS3), while Group B had a higher proportion with earlier stages of cataract (NS1). This difference is crucial as it could impact the efficacy of anesthesia methods used during surgery.

According to literature, the severity of cataracts can influence surgical outcomes and the choice of anesthesia (Smith et al., 2019).58 More advanced cataracts (NS2 and NS3) often require more precise and effective anesthesia to manage pain and ensure adequate mydriasis. This could explain why the combined use of topical Proparacaine with intracameral agents might show different efficacy compared to Proparacaine alone, particularly in cases with more severe cataract grading. For instance, studies have shown that advanced cataract grading can complicate surgery and necessitate different anesthesia approaches to ensure optimal outcomes (Hsu et al., 2020; Mathews et al., 2022).59,60

In summary, the significant differences in cataract grading between the groups suggest that the severity of the cataract could influence the outcomes of the anesthesia techniques used, highlighting the need for tailored approaches depending on cataract severity.

The findings align with existing research that highlights the challenges of maintaining optimal mydriasis throughout cataract surgery, particularly in complex cases where the pupil tends to constrict intraoperatively. Studies have shown that while intracameral agents like Phenylephrine and Tropicamide are effective in achieving initial mydriasis, their effectiveness can diminish over time due to various intraoperative factors

Summary

1. Study Focus: The study compares the effectiveness of two anesthesia methods during phacoemulsification cataract surgery: Proparacaine Hydrochloride (0.5%) alone versus Proparacaine with ICAM injections and also studies the efficacy of ICAM in achieving optimum mydriasis.
2. Anesthesia Techniques: Proparacaine alone provides surface anesthesia, while the combined method offers deeper anesthesia and better pupil dilation.
3. Patient Demographics: The age distribution of patients aligns with typical cataract demographics, with most patients being over 50 years old.
4. Sex Distribution: No significant difference in sex distribution was found between the groups, suggesting sex does not impact anesthesia efficacy in this context.
5. Preoperative Visual Acuity: Both groups had varying levels of visual acuity, with no significant differences between them, indicating a balanced comparison.
6. Hypertension History: Both groups had an identical distribution of hypertension, ensuring that this comorbidity did not confound the study results.
7. Diabetes History: A significant difference in the prevalence of diabetes was observed, which could potentially influence the outcomes related to anesthesia effectiveness.
8. Laterality: No significant difference in the laterality of the eye surgeries was observed between the groups, ensuring an unbiased comparison.
9. Cataract Grading: Significant differences in cataract grading were found between the groups, with Group A having more advanced cataracts, which could impact anesthesia efficacy.
10. Intraoperative Pain: Group B, which received the combined anesthesia, reported significantly less intraoperative pain compared to Group A.
11. Postoperative Pain: Group B also experienced significantly less postoperative pain, highlighting the effectiveness of the combined anesthesia method.
12. Mydriasis: While both groups achieved initial optimal mydriasis, Group B showed better maintenance of pupil dilation during surgery.
13. Gender and Pain: No significant gender-based differences in pain perception were found, suggesting that anesthesia effectiveness is similar for both male and female patients.
14. Cataract Grading and Pain: Higher cataract grades were associated with increased intraoperative pain,

Volume 8, Issue 6; November-December 2025; Page No 624-633

indicating a need for more effective anesthesia in advanced cases.

15. Conclusion: The combined use of Proparacaine with intracameral agents was more effective in managing pain and maintaining mydriasis during cataract surgery, particularly in complex cases.

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Volume 8, Issue 6; November-December 2025; Page No 624-633

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Volume 8, Issue 6; November-December 2025; Page No 624-633

Journal of Cataract & Refractive Surgery, 43(8), 1073- 1078.

Volume 8, Issue 6; November-December 2025; Page No 624-633