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Pre-operative minimal-cycloplegia mydriasis for capsulorrhexis in hypermature intumescent cataract

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ABSTRACT

Background: Conventionally adrenergic-anticholinergic combination eye drops (e.g., phenylephrine-tropicamide) are used for pre-operative pupillary dilatation in cataract surgery. This achieves synergy in dilatation, but anticholinergic-induced cycloplegia makes already tense lens-capsule of intumescent cataract more taut, and completion of capsulorrhexis becomes difficult, often resulting in Argentinian flag sign, peripheral extension. An alternative mydriasis-without-cycloplegia strategy (phenylephrine) is also tried for better maintenance of mydriasis but its capsule-slackening effect was not thought of. Making best of both, we practice a 'minimal-cycloplegia mydriasis' approach (MCM) comprising of 0.25% tropicamide and 5% phenylephrine, instilled in succession. This study was planned to compare our MCM regimen with the conventional fixed-dose-combination regimen of 0.8% tropicamide and 5% phenylephrine (Standard). **Objectives:** To compare the ease and smoothness of capsulorrhexis and relative incidence of complications, in hypermature intumescent cataract surgery, between ocular instillation of alternative 'MCM' regimen and the traditional 'Standard' regimen.

Materials and Methods: The study used a prospective observational 2-arm comparison design. The study commenced with due approval of Institutional Ethics Committee. Sixty-one (61) patients (age range: 42-72yrs, number of Male: Female 19:42) undergoing hypermature intumescent cataract surgery by standard SICS+IOL technique and in whom either of two regimens, MCM or 'Standard' were used for pupillary dilatation, were observed. Outcome analysis was done by Fisher's Exact Test.

Results: Out of a total of 61 cases, 29 received MCM regime and 32 received 'Standard' cycloplegic dilator. Difference in dilatation between two groups was statistically non-significant. Frequency of completed rhexis and attainment of post-operative BCVA of 6/12 were higher with MCM regime: $p < 0.001$ and $p < 0.0005$ respectively. Anterior chamber reactions on first post-operative day was more frequent with MCM regime ($p < 0.01$), but was transient and cleared totally in a week.

Conclusion: Minimal-cycloplegia dilatation regime comprising of 0.25% tropicamide and 5% phenylephrine, instilled in succession may be preferred for capsulorrhexis in hypermature intumescent cataract.

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1. Introduction

Capsulorrhexis in hypermature intumescent cataract remains a challenge till today. Conventionally adrenergic-

anticholinergic combination eye drops (e.g., phenylephrine-tropicamide) are used for pre-operative pupillary dilatation in cataract surgery. This achieves synergy in dilatation, but anticholinergic-induced cycloplegia makes already tense lens-capsule of intumescent cataract more taut,

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and completion of capsulorrhexis becomes difficult, often resulting in Argentinian flag sign, peripheral extension. An alternative mydriasis-without-cycloplegia strategy (phenylephrine) is also tried for better maintenance of mydriasis¹ but its capsule-slackening effect was not thought of. However on technical side some techniques have evolved over the years to solve the problem. Gimbel et al. (1990)² described a two-stage capsulorrhexis. First a small CCC is made, liquefied lens material is aspirated, then rhexis is secondarily enlarged. Bhattejee et al. (1999)³ first created an anterior capsular opening with a needle and then the liquid material was intermittently aspirated until the lens capsule was decompressed. Then the endoillumination technique, as described by Mansour, was used to complete the capsulorrhexis. Richards et al. (2002)⁴ used Neodymium: YAG laser to create an anterior capsulotomy just prior to surgery. Hausmann (1991)⁵ used a bipolar diathermic capsulotome as an alternative to capsulorrhexis to create a round anterior capsulotomy. Femtosecond laser Capsulotomy,⁶ Nanopulse capsulotomy⁷ have been introduced recently. Rajan M et al⁸ used Punchorrhexis- simultaneous puncture of the anterior capsule and decompression of the capsular bag done with phaco needle with burst phaco power. However none of the techniques could offer a gold standard, because these techniques are predominantly technology-dependent rather than science driven and requires high end costly instruments. In contrast, we exploited accommodation, a natural physiological phenomenon to solve the problem.

Cycloplegia during intumescent cataract surgery: A blessing or boon? The current practice is to use cycloplegic (Homatropin / Tropicamide/ Cyclopentolate) in pre-operative pupillary dilator regimen. However, cycloplegia makes capsule taut by increasing tension on zonules and thus makes capsule more prone to radial tear and run away. Therefore, Roy P⁹ developed a hypothesis of “minimal cycloplegic approach to dilatation” to facilitate favourable capsular behaviour during capsulorrhexis. As lens is in a relatively accommodated state in this approach, zonules remain relaxed, capsule flaccid and capsular behaviour is favourable rather than hostile.

2. Aims and Objectives

To study the relative ease and feasibility of capsulorrhexis in hypermature cataract surgery, with ocular instillation of an alternative regimen of a minimal cycloplegic tropicamide 0.25%, and 5% phenylephrine instilled in succession, compared to the standard practice of using the fixed-dose combination formulation of 0.8% tropicamide + 5% phenylephrine.

3. Materials and Methods

The study used a prospective observational 2-arm comparison design. The study commenced with due approval of Institutional Ethics Committee. Sixty-one (61) patients undergoing hypermature intumescent cataract surgery by standard MSICS+IOL technique and in whom either of the two regimens, MCM (‘Minimal-Cycloplegia Mydriasis’) or ‘Standard FDC’ were used for pupillary dilatation, were observed. Outcome analysis was done by Fisher’s Exact Test.

All surgeries were done by a single surgeon. Routine pre-operative assessment done in each case with USG of posterior segment to rule out posterior segment pathology. Pre-operatively after taking proper informed consent, the patients were randomly assigned to one of the 2 groups as follows:

3.1. ‘Minimal-cycloplegia mydriasis’ approach (MCM) group

Ocular instillation of 0.25% Tropicamide (1 in 4 dilution of commercially available 1% tropicamide, by re-constituting with CMC 0.5%) and Phenylephrine 5% eye drop.

Method of preparation of Tropicamide 0.25%. A Junior Resident after full OT scrub, wearing sterile gown, mask, cap and gloves prepare 1 in 4 dilution of Tropicamide 1% eye drop as follows: One cleaned pack of Tropicamide 1% eye drop was taken. With a 5 cc sterile syringe, 3/4th of the content was drawn out and discarded. Equal amount of CMC (carboxymethylcellulose eye drop 0.5%) drawn with another 5cc syringe from a clean pack of CMC eye drop and injected into the pack of Tropicamide eye drop to make it a 0.25% Tropicamide eye drop).

3.2. Standard FDC cycloplegia mydriasis group

Using the FDC eye drop of 0.8% tropicamide+ phenylephrine 5%

Sequence and Frequency of instillation of dilating drops given below:

1. Eye drop Phenylephrine 5% (Phenylephrine Hydrochloride U.S.P. 5%: 4 times at the interval of 5 minutes, starting 45 minutes before operation.
2. Eye drop Tropicamide 0.25 % (1 in 4 dilution of commercially available Tropicamide 1%). One drop 5-10 minutes after 4th instillation of Phenylephrine (if pupil was not adequately dilated after 10-15 minutes, one more drop of Tropicamide was instilled).

Eye drop Flurbiprofen: one drop when pupil is adequately dilated.

The surgeon was kept unaware as to which regimen of dilator was used.

Standard Manual Small Incision Cataract Surgery (MSICS) procedure as described in “Natchiar G. et al.

Manual of Small Incision Cataract Surgery: An alternative to instrumental phacoemulsification. 2nd ed; Aravind Eye Hospital & Postgraduate Institute of Ophthalmology, 2014”¹⁰ was adopted in all the cases. Salient features of the surgery in all the cases were as follows:- Surgeon: PR, Incision length: 6.5 mm. Incision site: Superior. Side port entry: at 9-o’clock position at limbus, Trypan Blue : used in all cases to stain the capsule. Viscoelastics used: HPMC, Capsulorrhexis: done with 26G needle cystitome through the side-port, starting at 5 to 6 o’clock position and continued anti-clockwise to meet the starting point.

The following points were noted during casulorrhexis:- Occurrence of Argentanian flag sign (Yes/No), Egress of liquefied cortex on nicking the capsule (Yes/No). Radial extension (o’clock position) (Can/ Can’t be brought back). Rhexis (Complete/ Incomplete).

All patients were put on standard post-operative medication and were followed up on 1st Post Operative Day, 7th Post Operative day, 3rd Post Operative week and 6th post-Operative week. On each follow-up visit, Best Corrected Visual Acuity (BCVA), Slit lamp examination and fundus examination was done. Post-operative A/C reaction (flare and cells) were graded as per SUN Working Group Grading Scheme (SUN=Standardization of Uveitis Nomenclature).

4. Results

Data are entered in excel sheet and analysis of results were done.

The age and sex distribution of the patients of the study was as follows Tables 1 and 2.

Outcome measure of the study was as follows: Pupillary dilatation (Table 3), Ease of Rhexis (Table 4), Attainment of BCVA ≥ 0.5 at 6th post- operative week (Table 5), and Freedom from complications (Tables 6 and 7).

The BCVA of ≥ 0.5 at 6th post-operative week is higher in Minimal Cycloplegia Mydriasis (24/29 i.e. 82.75%) than that in Fixed dose combination (FDC) mydriasis (11/32 i.e. 32.37%). This difference is highly statistically significant by Fisher’s Exact Test ($P = 0.0002$). (Table 5)

The chance of anterior chamber reaction (cells $\geq 3+$) in the 1st post-operative day is significantly higher in the Minimal Cycloplegia Mydriasis (MCM) than that in the Fixed dose combination (FDC) mydriasis. This difference is statistically significant.(Fisher’s Exact Test, $P = 0.0086$) (Table 6)

However, in both Alternative Minimal Cycloplegia Mydriasis (MCM) and Standard Fixed dose combination (FDC) mydriasis, the A/C reaction is transient and cleared by 1st post-operative week ($P = 1.0000$).

5. Discussion

Capsulorrhexis by “Minimal-Cycloplegia Mydriasis Approach” was first time reported by the author (PR) of this communication and preliminary reports of this study was displayed In: American Society of Cataract and Refractive Surgeons Annual Conference, San Diego 2019, Scientific Film section⁹ and presented in All India Ophthalmological Society Annual Conference, Indore 2019, in Free Paper section. No other report on this approach can be found in literature till date.

Capsulotomy/Capsulorrhexis in hypermature cataract: it is an established fact that the seat of presbyopia lies in the lens substance and not on the capsule. Therefore, lens-capsule reacts to accommodative effort even in presbyopic age. Development of in-the-bag presbyopic IOL speaks volumes for it.

In hypermature intumescent cataract capsule is more fragile in addition to impaired visibility of red reflex. Leakage of liquefied cortical matter and rhexis-tears can extend to the periphery due to high intra-lenticular pressure with sudden capsulorrhexis radialization.

In hypermature white cataract, besides staining the anterior capsule to increase its visibility, creation of a small capsulorrhexis which is secondarily enlarged after aspirating the liquefied milky lens contents can be attempted. Gimbel et al.² evaluated two techniques of capsulorrhexis for hypermature intumescent cataract: traditional one-stage capsulorrhexis and two-stage capsulorrhexis. They concluded that 2-stage rhexis helps prevent sudden radialization of capsulorrhexis and other intraoperative complications.

Femto-second laser assisted⁷ anterior capsulotomy/capsulorrhexis is said to be of special utility in hypermature intumescent cataract, being accurate, circular and centered, thus avoiding IOL eccentricity and tilt caused by asymmetric capsular bag contraction. Two-step femto-second laser assisted technique for hypermature intumescent cataract has been described with better 360° overlap of optic and implant stabilization.

Radio-frequency diathermy⁵ has also been successfully used to perform capsulorrhexis in hypermature intumescent cataract with varied results.

Different techniques of capsulorrhexis/capsulotomy have undergone progressive evolution to achieve perfection in size, shape, centration and overlap. Besides they also possess various disadvantages which have already been mentioned e.g. in laser assisted techniques higher costs are the major limiting factor. While manual CCC remains the gold standard and most commonly utilized technique of anterior capsulorrhexis, our study aims at improving this procedure in terms of ease and feasibility by pharmacomodulation of drugs used pre-operatively particularly in cases of hypermature white cataract for good visual and anatomical outcomes. Besides this technique

Table 1: Age distribution between the two mydriasis regimen, in the cohort undergoing hypermature intumescent cataract surgery by standard MSICS+IOL technique

	Minimal Cycloplegia Mydriasis (MCM)	Standad FDC
Mean Age \pm Standard Deviation (Range)	55.83 \pm 6.15 (42 –66)	60.41 \pm 5.97 (50 – 72)

Table 2: Gender distribution between the two mydriasis regimen, in the cohort undergoing hypermature intumescent cataract surgery by standard MSICS+IOL technique

	Minimal Cycloplegia Mydriasis (MCM)	Standad FDC
Male	13	6
Female	16	26

Table 3: Pupillary dilatation achieved by two mydriasis regimen

	Minimal Cycloplegia Mydriasis (MCM) regimen	Standad FDC mydriasis	P value
Mean Pupillary Dilatation	8.12 \pm 0.32 mm	8.28 \pm 0.36 mm	0.0728 (Not statistically significant)

*The two tailed student's t test indicates the difference of mean pupillary dilatation between MCM and Standard FDC mydriasis was statistically non-significant at P= 0.0728. (Table 3)

Table 4: Ease of doing Rhexis

Exposure		Outcome (Capsulorrhexis)		P value (Fisher's Exact Test)*
		Complete (n)	Incomplete (n)	
	Minimal Cycloplegia Mydriasis (MCM)	24	5	<0.001 (Statistically significant)
	Fixed dose combination (FDC) mydriasis	12	20	

* P value equals 0.0006 (<0.001) using Fisher's Exact Test thus showing that Ease of doing Rhexis measured in terms of frequency of completed rhexis to be higher in the minimal cycloplegia mydriasis as compared to that in standard FDC mydriasis (p<0.001- statistically highly significant) (Table 4)

Table 5: BCVA attained at 6 weeks postoperative in two mydriasis regimen

Exposure		Outcome BCVA		Pvalue (Fisher's Exact Test)
		6 \geq 6/12 (n)	< 6/12 (n)	
	Minimal Cycloplegia Mydriasis (MCM)	24	5	P<0.0005 (Statistically significant)
	Fixed dose combination (FDC) Mydriasis	11	21	

Table 6: Effect on anterior chamber reaction by two mydriasis regimen at 1st post-operative day

Exposure		Outcome A/C reaction		Pvalue (Fisher's Exact Test)
		Cells \geq 3+ (n)	Cells < 3+ (n)	
	Minimal Cycloplegia Mydriasis (MCM)	10	19	P<0.01 (Statistically significant)
	Fixed dose combination (FDC) mydriasis	2	30	

Table 7: Effect on anterior chamber reaction by two mydriasis regimen at 1st post-operative week

Exposure		Outcome		P value (Fisher's Exact Test) 1.0000 (Statistically not significant)
		A/C reaction At the end of 1 st week Cells >1+ (n)	Cells \leq 1+ (n)	
	Minimal Cycloplegia Mydriasis (MCM)	0.00	29	
	Fixed dose combination (FDC) mydriasis	0.00	32	

Table 8: Comparison of techniques of capsulorrhexis employed in white intumescent cataract

Author(year)	New Technique/ Application of Alternative Technique	No. of eyes studied in New/Alternative technique	No. of eyes studied in Conventional rhesis	P Value	Statistical significance level
GIMBEL et al 1991 ²	Two-stage capsulorrhexis	34	2933		p<0.05
Richards et al ⁴	Neodymium: YAG laser capsulotomy	25	-	-	-
Hausmann (1991) ⁵	Bipolar diathermic capsulotomy	25	-	-	-
Abell Chag Roberts 2014 ⁷	Femtosecond laser capsulotomy	804	822(by PCS)	-	-
Thompson ¹¹	Zepto nano pulse capsulotomy	38	-	-	-
Rajan M et al. 2018 ⁸	Punchorhexis	250	-	-	-
Roy P et al. 2020, the present study	Alteranative technique of preoperative pupillary dilatation by minimal cycloplegia mydriasis.	29	32	P = 0.0006	P<0.001

can be utilized for all patients even with poor financial conditions due to its low cost as compared with the laser assisted techniques.

The possible explanation of increased anterior chamber reaction in 1st post-operative day might be due to minimization of cycloplegic might cause micro twitching of iris resulting in dispersion of iris pigments. Our finding corroborates with findings of Iftikhar M et al (2021)¹ who mentioned in their review article about increased incidence of Iris-related complications (11 out of 30 eyes) in intracameral use of Phenylephrine without use of any cycloplegic.

Therefore, the technique used in our study merits consideration for use in hypermature white cataract patients.

6. Conclusion

1. This is the first time in literature that the challenge of capsulorrhexis in hypermature intumescent cataract was addressed by pharmacomodulation of preoperative pupillary dilatation.
2. In “Mnimal Cycloplegia Mydriasis” (MCM) approach, good pupillary dilatation compatible with performance of all steps of surgery was achieved.
3. In “Mnimal Cycloplegia Mydriasis” (MCM) approach, the outcome of hypermature intumescent cataract surgery was much better in term of Ease of rhesis and attainment of BCVA of 6/12 or more.
4. “Mnimal Cycloplegia Mydriasis” (MCM) approach might cause increased anterior chamber reaction in 1st post-operative day. But the reaction is transient and went off completely in all cases by 1st week.

7. Recommendation

Therefore, the “Mnimal Cycloplegia Mydriasis” (MCM) technique used in our study merits consideration for use in hypermature cataract surgery.

8. Source of Funding

None.

9. Conflict of Interest

None.

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