Indian Journal of Basic and Applied Medical Research; March 2023: Vol.-12, Issue- 2 , P. 157 - 164
DOI: 10.36855/IJBAMR/2022/98215.5632

Original article:

Comparison of mydriasis and surgical outcome in manual small incision cataract surgery using topical eye drops versus intracameral injection in a tertiary care centre of Karnataka: A single blind randomized controlled trial

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Date of submission: 18 January 2023
Date of Final acceptance: 05 March 2023
Date of Publication: 30 March 2023
Source of support: Nil
Conflict of interest: Nil

Abstract

Background: In India, manual small incision cataract surgery is popular and probably the most performed surgery in community based high volume surgical campaigns. Modern cataract surgery either by phacoemulsification or manual small incision cataract surgery (MSICS), both require good pupillary dilatation. The present study has evaluated the efficacy, sustainability and safety of intracameral mydriasis in performing manual small incision cataract surgery under peribulbar anaesthesia in comparison to traditional tropical eye drops as there are very limited studies.

Methods: A single blind randomized controlled trial was conducted among patient attending ophthalmology OPD. Detailed history of the patient with complete ocular examination with slit lamp and fundus of patient was viewed with direct and indirect ophthalmoscope, and slit lamp bio microscopy with 90 D lens. Patient were randomly subdivided into two groups, that is, topical and intracameral group.

Results: A total of 34 study subjects were enrolled in both the study groups with majority of the participants in both the study group were in the age group of 51 to 60 years followed more than 60 years of age and least number of patients in the age group of 41 to 60 years. Gender-wise distribution of study groups was also comparable. The mean duration of surgery among patients in topical mydriatic group was relatively higher when compared to intracameral mydriatics group. There was statistically no significant difference in the pupil size between the two groups.

Conclusion: There was no significant difference in pupil dilation between the topical and intracameral mydriatics with no significant difference in the uncorrected, best corrected, and LogMAR visual acuity.

Keywords: mydriatics, intracameral, cataract, MSICS, peribulbar anaesthesia

Introduction

Blindness is a major public health problem not only to the individual but also to the family and community at large. The world health organization estimates an annual loss of US$ 411 billion due to visual impairment and a global prevalence of vision impairment of at least 2.2 billion people of which approximately 1 billion suffering from preventable blindness. Cataract is one of the leading cause of preventable blindness worldwide[1] and in India it contributes to almost two-third (62.6%) cases of blindness. [2]

In India, manual small incision cataract surgery is popular and probably the most performed surgery in community based high volume surgical campaigns. Modern cataract surgery either by phacoemulsification or manual small incision cataract surgery (MSICS), both require good pupillary dilatation, which at present, achieved by repeated administration of mydriatic/cycloplegic and NSAID (non-steroidal anti-inflammatory drug) eye drops.[3]

The maintenance of mydriasis and the controls of postoperative pain and inflammation are more important and critical for the safety and success of cataract and intraocular lens replacement surgery. Topical drops using standard regimen of alternative tropicamide 0.8% plus phenylephrine 5% drops at 15 min interval but topical method of dilation of pupil usually depends on additional manpower, increased preparation time for patient and cause potential contamination of corneal surface.[4] Topical agents are also known to cause non-ocular reactions such as dry mouth, tachycardia, headache, allergic reactions[5] and post-operative ophthalmic complication like difference in endothelial cell loss, inflammatory reaction and postoperative corneal swelling.[6] To obviate these disadvantages the intracameral mydriatics were introduced. Though intracameral mydriatics is proven to be a safe approach but prolapse of cataractous nucleus into the AC during surgery has been reported[7] and mydriasis may not be sustained for entire duration of surgery.[4]

In the present study we have evaluated the efficacy, sustainability and safety of intracameral mydriasis in performing manual small incision cataract surgery under peribulbar anaesthesia in comparison to traditional tropical eye drops as there are very limited studies.

Objectives

To compare the mydriatic effect of topical eye drops with intracameral injection in manual small incision cataract surgery.

To study efficacy and safety of intra operative intracameral mydriasis in manual small incision cataract surgery.

Methods

A single blind randomized controlled trial was conducted among patient attending ophthalmology OPD with complete examination by silt lamp and who were diagnosed as cataract at a tertiary care hospital (Medical college) in Chitradurga district of Karnataka, during the period of 1st March 2021 – 31st August 2022 were considered. An informed written consent was obtained from all the study participants before including them in the study.

Sample size calculated using open EPI software using 95% confidence interval and 80% of power of study. It was considered that % unexposed with outcome as 40% and we are expecting odd ratio of 4. We enrolled a total of 34 cases in each study group. Patients with cataract in one or both eye, in the age group of 40 to 70 years, undergoing cataract surgery in our institute and consented for the study were considered for the study. Patients with pseudo-exfoliation disease, previous intraocular surgery, pupillary deformity, hypersensitivity to any medications were excluded from the study. Factors affecting pupil size such as diabetic status, retinal

disorders (CRVO, BRVO, optic nerve disease, uveitis), and patients on medications affecting the same (pilocarpine, alpha blockers, NSAIDs) were excluded from the study.

Detailed history of the patient with complete ocular examination with slit lamp and fundus of patient was viewed with direct and indirect ophthalmoscope, and slit lamp bio microscopy with 90 D lens. Patient were randomly subdivided into two groups, that is, topical and intracameral group. Patient allocated to topical mydriatic group underwent pupillary dilation on the day of surgery with pre-operative topical drugs using the standard regimen of alternative tropicamide 0.8% plus phenylephrine 5% drops at 15 min interval for 1 hour before surgery. Patient allocated to intracameral mydriatic group were not administered with any topical drops. But pupillary dilation was achieved intra operatively by surgeon by injecting a solution containing phenylephrine 0.31% + lidocaine 1% + tropicamide 0.02% immediately after first entry into anterior chamber.

Patient from both the group were administered peribulbar anesthesia. The pupil size was measured five times in both groups i.e., (a) just before peribulbar block, (b) just before patient was made to lie on operating table, (c) one minute after entering anterior chamber in topical group and 30 seconds after injecting intracameral mydriatic in intracameral group, (d) just after extraction of nucleous from anterior chamber and (e) just before IOL implantation.

During the pre-operative period the pupil size was measured under a slit lamp. Intraoperative pupil size was measured using Castroviejo surgical calipers under fixed microscope illumination and magnification at different stage of surgery. The authors followed for standard operative procedures for MSICS with peribulbar anesthesia. If the mydriasis was inadequate intraoperatively, the surgeon decided either to reinject intracameral mydriatic solution or to apply topical drops whenever required.

The data collected was entered in the MS Excel master sheet. Data was tabulated and analyzed using software Statistical Package for Social Sciences (SPSS) version 22. Categorical data have been presented as numbers and percentages (%) and quantitative data in terms of mean and standard deviation. Categorical variables have been analysed using Pearson’s chi-square test and Fisher exact tests (when the expected count of 20% of cells is less than 5). Quantitative variables have been analysed using Student T test.

Ethical clearance:

Ethical clearance has been obtained from the institutional ethics committee.

Results

A total of 34 study subjects were enrolled in both the study groups with majority of the participants in both the study group were in the age group of 51 to 60 years followed more than 60 years of age and least number of patients in the age group of 41 to 60 years. Gender-wise distribution of study groups was also comparable (table 1).

Table 1: Socio-demographic characteristics of study subjects

Parameter	Topical group	Intracameral group	p-value
Age group			
41 to 50 years	6 (17.7%)	5 (14.7%)	0.860
51 to 60 years	18 (52.9%)	17 (50.0%)	
> 60 years	10 (29.4%)	12 (35.3%)	
Gender			
Male	16 (47.1%)	15 (44.1%)	0.807
Female	18 (52.9%)	19 (55.9%)	
Total	34 (100%)	34 (100%)	

The study groups were also analysed for comparison of baseline parameters. The study participants in both the groups were analysed for diagnosis, uncorrected visual acuity and best corrected visual acuity. There was statistically no significant difference in any of these parameters between the two study groups (table 2).

Table 2: Baseline parameters of study subjects

Parameter	Topical group	Intracameral group	p-value
Diagnosis			
LE SIMC	9 (26.5%)	7 (20.6%)	0.899
LE SMC	6 (17.6%)	5 (14.7%)	
RE SIMC	10 29.4%)	11 (32.4%)	
RE SMC	9 (26.5%)	11 (32.4%)	
Total	34 (100%)	34 (100%)	
Uncorrected visual acuity (Mean ± SD)			
Right eye	3.02 ± 0.87	3.02 ± 0.87	1.000
Left eye	2.85 ± 1.05	2.91 ± 1.05	0.818
Best corrected visual acuity (Mean ± SD)			

www.ijbamr.com P ISSN: 2250-284X, E ISSN: 2250-2858

Right eye	2.03 ± 0.72	2.0 ± 0.74	0.868
Left eye	2.23 ± 0.74	2.1 ± 0.74	0.626

The mean duration of surgery among patients in topical mydriatic group was 14.12 ± 2.16 minutes whereas the same for intracameral mydriatics group was relatively less (12.53 ± 1.46). This difference in duration of surgery was found to be statistically significant with a p value of 0.001.

The measurement of pupil size was measured five times in both the study group. The baseline readings of pupil size in both the study groups were comparable with a mean of 7.5 ± 0.86 mm in topical group and 7.44 ± 0.96 mm among intracameral group. There was statistically no significant difference in the pupil size between the two groups. Similar were the findings when the pupils were measured just before the patients were made to lie on operating table and one minute after entering anterior chamber. The mean pupil size was relatively higher in intracameral group (5.06 ± 0.88 mm) just before extraction of nucleous from anterior chamber whereas the same for topical group was 4.76 ± 0.78 mm but this difference was not found to be statistically significant (p value – 0.151). However just after extraction of nucleous from anterior chamber pupil size was relatively higher in topical group (5.15 ± 0.92 mm) when compared to intracameral group (4.29 ± 0.87 mm) and this difference was found to be statistically significant with a p value of less than 0.001 (table 3).

Table 3: Pupil size measurement at various interval among both study groups

Pupil size (Mean ± SD)	**Topical group**	**Intracameral group**	**p-value**
P1: Just before peribulbar block	7.5 ± 0.86	7.44 ± 0.96	0.719
P2: Just before patient lie on operating table	7.38 ± 0.98	7.55 ± 0.82	0.426
P3: One minute after entering anterior chamber	5.2 ± 0.88	5.14 ± 0.92	0.789
P4: Just after extraction of nucleous from anterior chamber	4.76 ± 0.78	5.06 ± 0.88	0.151
P5: Just before IOL implantation	5.15 ± 0.92	4.29 ± 0.87	<0.001

The nucleus size was grade 3 in 47.1% of study subjects of topical group and 38.2% of the intracameral group followed by grade 2 in 41.2% of participants in topical group and 38.2% subjects in intracameral group (figure 1). This difference in nucleus grade was not statistically significant (figure 1). The LogMAR vision in topical group was 1.53 ± 0.56 and 1.5 ± 0.51 in the intracameral group with statistically no significant difference between the study groups (p value – 0.822).

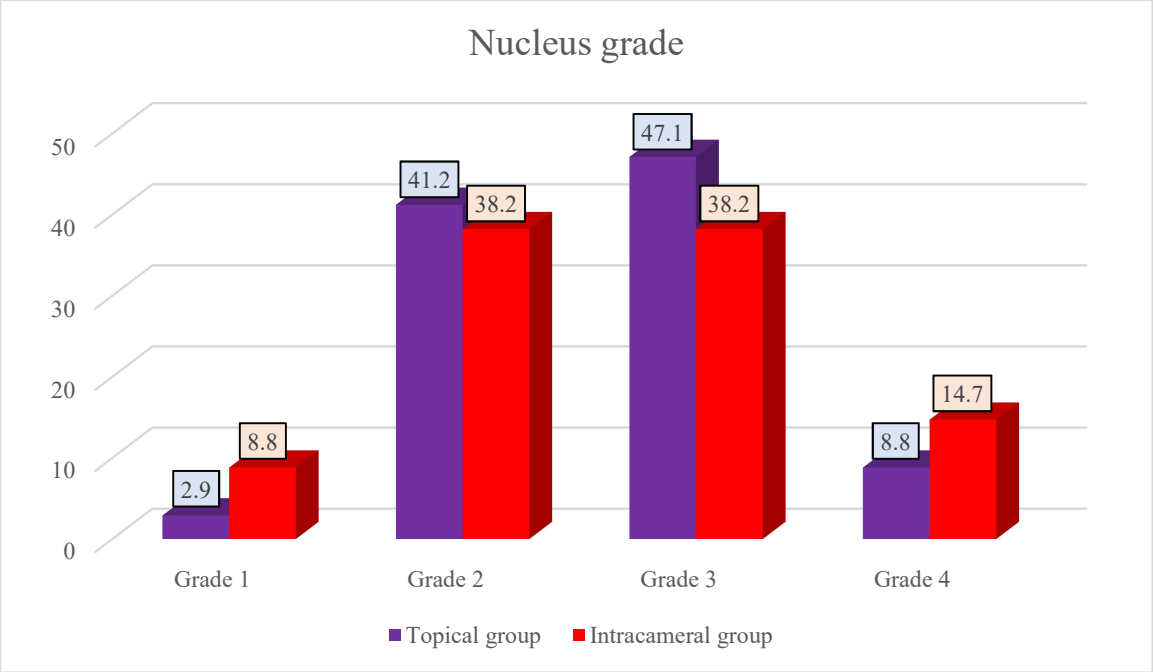

Figure 1: Distribution of the study group according to nucleus grade

Discussion

Cataract is an important preventable cause of blindness. Modern cataract surgery either by phacoemulsification or manual small incision cataract surgery (MSICS), both require good pupillary dilatation, which is achieved by repeated administration of mydriatic/cycloplegeic and NSAID (non-steroidal anti-inflammatory drug) eye drops.[3] As there are very limited studies, in the present study we have evaluated the efficacy, sustainability and safety of intracameral mydriasis with traditional tropical eye drops in performing manual small incision cataract surgery under peribulbar anaesthesia.

In the present study, majority of the participants in both the study group were in the age group of 51 to 60 years (52.9% in topical group and 50% in intracameral group). A little more than half of study population in both groups were women. Similar were the findings in a study by Ajay et al, wherein about 54.1% of the topical group and 52.38% of the intracameral group were males[4] whereas in a study by Morgado et al, the proportion of females was relatively higher in both groups, with about 66.6% of the cases in topical group and 70.0% in intracameral group being females.[8]

In the present study the mean duration of surgery was significantly lower in intracameral mydriatics group when compared to topical group (12.53 ± 1.46 vs 14.12 ± 2.16 minutes). Contrary to the findings of our study Morgado et al observed mean surgery duration in topical group was 8.3 minutes and 12.3 minutes in the intracameral group.[8] Ajay et al[4] and Shilpa Sunil et al[9] in their study observed no significant difference in surgical time between the two study groups.

The Pupil size was 7.5 mm in topical group which declined to 4.76 just after exctraction of the nuclaus from anterior chamber. The initial pupil size was 7.44 in intracameral group and declined to 4.29 just before IOL impantation. There was a statistically signifcant difference in mydriasis just before IOL implantation. A study by Ajay et al reported that, the mean preopertaive dilation size was 7.5 mm in topical group and 7.4 mm in the intracameral group.[4] A study by Morgado et al noted that, best pupillary dilations were achived in the younger patients with good and rapid topical mydriasis.[8] A study by Lay Suan et al reported that, the mean pupil dilation

between the intracameral group (4.86 mm) and the topical group (4.88 mm) which was not statistically significant. The mean pupil size before capsulorhexis in the topical group was significantly larger than in the intracameral group. The pupil in the in the intracameral group continued to dilate during surgery than in topical group.[10] A study by Shilp Sunil had noted no significant difference in the dilation of pupil between intracameral lidocaine and topical mydriatic before dilation, after dilation and at the end of surgery.[9]

The most common nucleus grades were grade 2 and grade 3 in both the study groups with statistically no significant difference. Similar were the findings of study conducted by Ajay et al[4] wherein grade 2 was most commonly observed (45.9% in topical group and 49.2% in intracameral group) followed by grade 3 (26.22% in topical group and 25.39% in intracameral group). LogMAR vision also didn't have any statistically significant difference which is in agreement with the study done by Ajay et al.[4]

Conclusion

The authors conclude that there was no significant difference in pupil dilation between the topical and intracameral mydriatics (except just before IOL implantation) with no significant difference in the uncorrected, best corrected, and LogMAR visual acuity between the topical and intracameral mydriasis. However, the average duration of surgery was relatively lower with the use of intracameral mydriatic.

Limitations

The present study was able to bring out important facts about the mydriasis using topical and intracameral agents but was conducted in a single tertiary care centre with limited number of study subjects. Further research in this direction by conducting randomized control trials involving larger study subjects can help to bring out additional information about topical and intracameral mydriatics in MSICS.

Conflict of interest: Nil

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