Original Article

Use of Combination Intracameral of Mydriatics and Anesthetics vs Topical Mydriatics in Small Incision Cataract Surgeries for Better Pupillary Dilatation

Mahmud-ul-Huda[1], Md Abdus Salam[2], Md. Zinnurain[3], Abrar Zahin[4], Md. Miftahul Hossain Chowdhury[5], Zakia Sultana[6], Subarna Roy[7]

Abstract

Background: Small incision cataract surgery (SICS) is one of the cost-effective surgical procedures In small incision cataract surgery (SICS) topical mydriatics are used conventionally. Combination of intracameral mydriatics and anesthetics are used in recent years. The aim of this study was to compare efficacy of combination of intra cameral (IC) administration of mydriatics and anesthetics (tropicamide 0.02%, phenylephrine 0.31% and lidocaine 1%) with topical mydriatics (tropicamide 0.8% and phenylephrine 5%) in small incision cataract surgery (SICS). **Methods:** This is a prospective, interventional study done in Department of Ophthalmology, Sheikh Hasina medical college Hospital, Jamalpur. The study includes 126 eyes of 126 patients who were admitted in the inpatient department of SHMCHJ for cataract surgery from 27 April, 2022 to 24 May, 2022. Patients were randomized into two groups: Intracameral mydriatics (ICM) group and Topical mydriatics (TM) group. IC group received 0.2 ml intra cameral injection of mydriatics and anesthetics just after the first incision and topical group received preoperative topical regimen of one drop each of tropicamide 0.8% and phenylephrine 5% repeated three times. The size of the pupil was measured per operatively with caliper. **Results:** A total of 126 patients were enrolled. The mean pupil diameter in ICM group was 7.6 mm ± 0.72 before capsulorhexis, 7.3mm ± 0.78 before lens implantation and 7mm ± 0.83 before end of surgery. In case of TM group the diameter was 7.9 mm ± 0.51, 7 mm ±0.68 and 6.7 mm ±0.85 respectively. A pupil diameter ≥ 6mm was achieved and maintained, till the end of surgery, 95.7% in ICM group and 86.3% in TM group. **Conclusions:** SICS can safely be done with intracameral combination of tropicamide, phenylephrine, and lidocaine as well as can be a good alternative to standard topical regimen. Optimum pupillary diameter is maintained in ICM group which ensures proper mydriasis .

Key words: Small incision cataract surgery, intra-cameral injection, mydriatics, anesthetics, mydriasis, stable pupil dilatation.

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Introduction

In Bangladesh, cataract is the leading cause of avoidable blindness . Currently surgical removal of the opaque lens with implantation of intraocular lens is the only treatment option available to restore vision in cataract . Small incision cataract surgery (SICS) is one of the cost-effective surgical procedures[1,2]. Among Many surgical techniques, SICS is considered the best procedure to address huge number of backlog and increasing number of cases in low and medium income countries like Bangladesh[3]. SICS is less time consuming, requiring less technology and most importantly less expensive; but the outcome is almost similar in comparison with phacoemulcification. That is why it is ideal for developing countries[4,5]. Dilatation of pupil is a prerequisite and a key factor of SICS. It must be adequate and stable throughout the surgical procedure. Topical mydriatics eye drops are used preoperatively to dilate pupil for SICS as a standard method. Advantages and limitations of abovementioned methods are summarized by authors and many of the newer approaches used that have been studied last 30 years are described.

1. Associate Professor (ophthalmology), Sheikh Hasina Medical College, Jamalpur
2. Assistant Professor (ophthalmology), DGHS
3. Associate Professor (ophthalmology), Mymensingh Medical College Hospital, Mymensingh
4. Resident, Ispahani Islamia Eye Institute and Hospital, Dhaka
5. Associate Professor, Ophthalmology, National Institute of Ophthalmology & Hospital, Dhaka
6. Assistant Professor, National Institute of Ophthalmology and Hospital, Dhaka
7. Epidemiologist, National Institute of Ophthalmology and Hospital, Dhaka

Address of correspondence:
Dr. Md. Mahmud-ul-Huda
Associate Professor (ophthalmology)
Sheikh Hasina Medical College, Jamalpur.
E-mail: drlavlu@yahoo.com

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[6,7] Now a days, there is an increase in the use of intracameral mydriatics in cataract surgery as an alternative to the traditional topical regimen.[8–10] Studies using IC anaesthetic reported increased patient comfort, especially during IOL implantation and greater surgeon satisfaction.[11,12] So, a combination of topical anesthesic and IC mydriatics and anesthetics could increase the intra-operative comfort of both the surgeon and the patient, as well as good mydriasis. This sterile ready to use solution also reduces the pre-operative patient preparation time. In 2015, the first ready to use, standardized, commercially manufactured medicinal product Mydrane (Laboratoires Thea, France) was approved for use in several European countries. In Bangladesh, this product is also approved and available from 2022. The injection is available at 1 ml/ampoule. To achieve mydriasis and anesthesia, it is injected into the anterior chamber at the beginning of the surgery. 0.2 ml is injected into the anterior chamber which contains 0.04 mg of tropicamide, 0.62mg of phenylephrine hydrochloride and 2 mg of lidocaine hydrochloride. IC mydriatic and anesthetic is a salt and pH-balanced solution. Data from a phase III clinical trial have shown that it :

- induces stable mydriasis within a very short time and has a good safety profile,
- allows for reductions in doses of active substances compared with eye drops,
- speeds up surgery preparation because it is administered once at the beginning of surgery and does not need to be administered during the preoperative period.[13]

Methods

Study design

This was a prospective study to compared the efficacy and safety of IC mydriatic and anesthetic (ICM group) to a standard topical mydriatic regimen (TM group) for cataract surgery. The study was designed, performed, and reported in accordance with the ethical principles discussed in the Declaration of Helsinki and the Strengthening the Reporting of Observational Studies in Epidemiology guidelines.[14] The study was approved by the Ethical Committee of Sheikh Hasina medical college, Jamalpur, Bangladesh.

Patient selection

All patients admitted for cataract surgery in Sheikh Hasina medical college, Jamalpur, Bangladesh from 27 April 2022 to 24 May 2022. Proper informed consent was taken from every patient. Age of the patients were 35 – 110 years, scheduled for SICS. Patients with a history of intraocular surgery or combined procedures, iatrogenic, traumatic or congenital cataract, progressive corneal disease, history of ocular trauma, infection or inflammation within the previous three months, pseudoexfoliation and exfoliation syndrome were excluded from the study. The dilated pupillary diameter of ≥ 6mm was included in the study. World health organization (WHO) Lens Opacities Classification scale was used to assess lens maturity.

Demographics

Out of 126 patients, 56 patients (44.4%) were male and 70 patients (55.6%) were female. The mean age of the patients was 61.91 ±7.2 years. The median age was 60 years (range 35-110 years).

Ocular history

Ocular findings (anterior segment) Specific anterior segment abnormalities were noted in the study questionnaires.

Cataract grading

World Health Organization (WHO) grading system was used. In 2002, WHO published a simplified cataract grading scale. Nucleus is best graded with slit beam at 30 to 45 degree angle to the cataract. In an early cataract, it is found that the central nucleus is actually clearer than the anterior and posterior embryonic layers of the lens.

NS I+: Nucleus clearer than anterior/posterior sections
NS II+: Nucleus equal to the anterior/posterior sections (same opacity level throughout)
NS III+: Nucleus denser than anterior/posterior sections
NS IV+: Brunescent: Cataract completely opaque/ brown

Administration of drug

In TM group, 3 drops of a combination of tropicamide 0.8% and phenylephrine 5% was given at 15-minute intervals before surgery. In the ICM group intra cameral injection of tropicamide 0.02%, phenylephrine 0.31% and lidocaine 1% was administered at the beginning

of the surgery. ICM group was supplemented with topical anesthetic eye drops and gel. Periorbital anesthesia was applied in TM group.

All surgeries were done by a single surgeon. Pupil diameter was measured during operation by the surgeon at following stages of the procedure:

1. Just before corneal incision
2. Just before capsulorrhaxis
3. Before IOL implantation
4. Before subconjunctival injection

The time taken for maximum dilatation after IC injection was measured also. The measurements were done with a surgical caliper. Any additional medications that were used to obtain or maintain mydriasis or anesthesia preoperatively were also noted.

Statistical Analysis

Statistical analysis was performed on SPSS 28 . Data were presented in tables and figures .

Result

130 patients were randomly selected from 27 April 2022 to 24 May 2022, who consented for the study. 4 patients were excluded due to pupil dilated less than 6 mm and some personal problem of the patient. So, 126 patients underwent cataract surgery were included in this study. 46 patients were in ICM group (Intra-cameral mydriatics) and 80 patients in TM (Topical mydriatics) group. 56 patients (44.4%) were male and 70 patients (55.6%) were female. The mean age of the patients was 61.91 ±7.2 years. The median age was 60 years (range 35-110 years). According to Nuclear sclerotic (NS) grading of WHO 118 patients (93.7%) had nucleus sclerosis. Most of the patients had grade N3 (39.7%) and N2 (27%) opacities [Table I].

Table I : Distribution of nuclear sclerotic grading of cataract (WHO)

WHO grading scale	Number of patients	%
No NS	8	6.3
NS I	12	9.5
NS II	34	27
NS III	50	39.7
NS IV	22	17.5

In this study, 6.3% had no nuclear sclerosis, 9.5% had nuclear sclerosis I, 27% had nuclear sclerosis II, 39.7% had nuclear sclerosis III and 17.5% had nuclear sclerosis IV.

Table II : The mean and median pupillary diameters at various stages of surgery in ICM subgroup.

Stage of surgery	Mean papillary dilatation(mm)	SD (mm)	Median (mm)	Rang (mm)	≥ 6mm (%)
Just before surgery	3.25	±0.54	3	2-4	97.8
Before capsulorhexis	7.6	±0.72	8	6 – 10.5	100
Before intraocular lens implantation	7.3	±0.78	7	4.5 – 10	97.8
Before the end of surgery	7	±0.83	6	4 – 9	95.7

In this study, it was found that in ICM group, the mean pupillary diameters at various stages were before capsulorhexis 7.6 mm, before IOL implantation 7.3 mm and before end of surgery 7 mm. In case of ICM group, 97.8% cases achieved papillary diameter ≥ 6mm before surgery, 100% cases achieved this diameter before capsulorhexis, it was maintained up to before IOL implantation in 97.8% and in 95.7% cases until end of the surgery.

Table III : Mean and Median Pupil Diameters in the TM subgroup

Stage of surgery	Mean(mm)	SD (mm)	Median (mm)	Rang (mm)	≥ 6mm (%)
Before capsulorexis	7.9	±0.51	8	6 – 9	100
Before intraocular lens implantation	7	±0.68	7	4- 9	91.3
Before the end of surgery	6.7	±0.85	7	4 – 9	86.3

In this study, it was found that in TM group, the mean pupillary diameters at various stages were before capsulorhexis 7.9 mm, before IOL implantation 7 mm and before end of surgery 6.7 mm. In case of TM group, 100% cases achieved this diameter before capsulorhexis, it was maintained up to before IOL implantation in 91.3% and in 86.3% cases until end of the surgery.

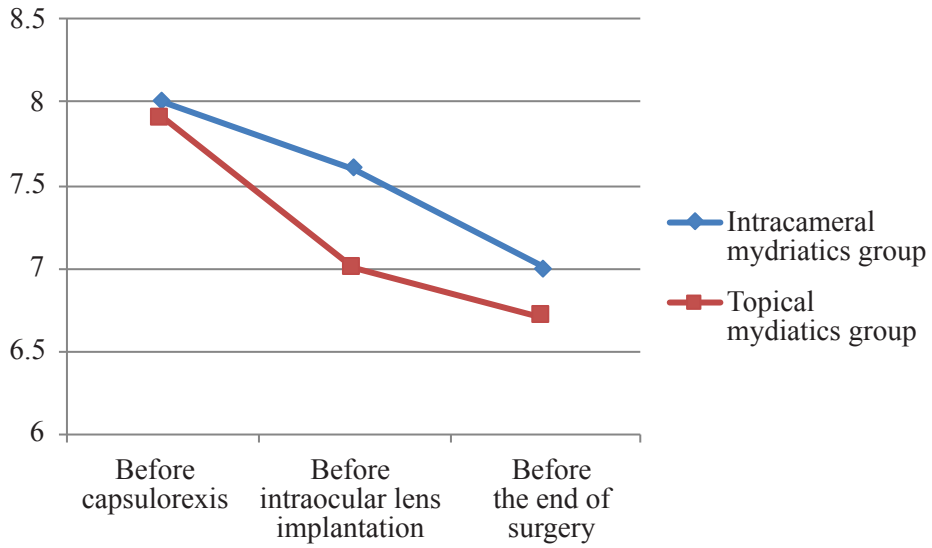

Figure 1 : Comparison of pupilary dilatation at different stages of surgery between two groups.

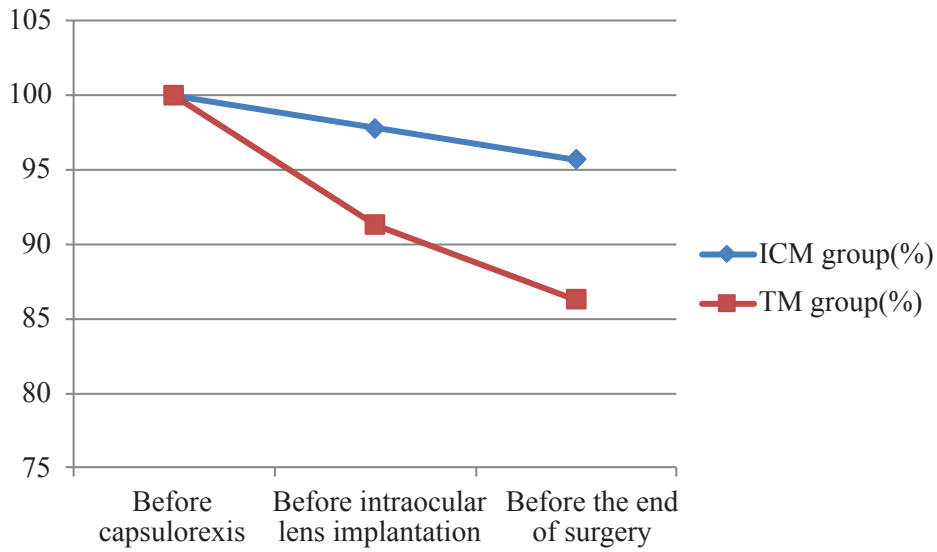

Figure 2 : Pupil maintaining ≥ 6 mm diameter (%) in ICM and TM group

Discussion

Obtaining adequate, quick and stable mydriasis is one of the key points of every cataract surgery procedure . Mydriatic eye drops are the standard method for pupil dilation in cataract surgery, but their limitations have provoked a search for different techniques[15]. Mydrane is the first industrially manufactured and standardized mixture of mydriatics (tropicamide and phenyl ephrine hydrochloride) and anesthetic (lidocaine) for intrcameral injection. In our study we found Intracameral administration of mydriatics analgesics injection induces rapid mydriasis and it maintains mydriasis better than topical mydriatics and can be an alternative to topical mydriasis in cataract surgery[16, 17,18]. Multiple trials conclude, that it is comfortable for surgeons, patients and medical staff (no need for multiple mydriatic drop administration preoperatively, patients reported to be more comfortable especially before IOL insertion) and cost-effective for hospitals - it shortens presurgical and surgical procedures. Additionally, the presence of lidocaine 1% in Mydrane led to improved intraoperative anaesthesia, with lower patient discomfort during IOL insertion (the most active phase of surgery) compared with the standard topical regimen. Our findings are similler to the study done by G. nazim-lipski et al of Jagiellonian University Medical College, Poland in 2020 [16, 17, 19].

We also assessed secondary efficacy parameters by determining the percentage of patients in whom a pupil diameter ≥ 6 mm was achieved at defined time points during surgery. A study by Donnenfeld et al. stated that the U.S. Food and Drug Administration defines intraoperative miosis as a pupil diameter smaller than 6.0 mm at any time during surgery. It is worth emphasizing that such miosis was reported in only 2.3% (n = 3) of patients before capsulorhexis, in 6.4% (n = 8) of patients before lens implantation and 10.3% at the end of the surgery. Mydriasis was achieved after a single injection of Mydrane without any preoperative mydriasis in a real-life patient population[20].

The advantage of the study was conducted in academic hospitals. The operating doctor was with extensive surgical experience. It is also important that our study population had hard cataracts, because more than 57% of the patients had WHO grade NIII and NIV .We know that hard nuclear cataract has more chance to touch the iris and cause reduce dilatation of the pupil per operatively SICS.

Limitations of this study relate mainly to a small number of patients in both analyzed groups. There was no control group. No data were collected on the type of viscoelastic, surgical settings, and the time savings.

Conclusion:

The mean pupilary diameter was ≥ 6 mm was achieved and it was also maintained in stages of Small Incision Cataract Surgery (SICS).The intracameral anesthetics also comfortable for both the patient. So SICS can safely be done with intracameral combination of tropicamide, phenylephrine, and lidocaine.and can be a good alternative to standard topical regimen.

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