e-ISSN: 0975-1556, p-ISSN:2820-2643

Available online on www.ijpcr.com

International Journal of Pharmaceutical and Clinical Research 2024; 16(8); 1226-1232

Original Research Article

A Study on Trypan Blue Dye as an Adjunct for Safe Small Incision Cataract Surgery in Mature Cataract Patients

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Received: 25-05-2024 / Revised: 23-06-2024 / Accepted: 26-07-2024
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Conflict of interest: Nil

Abstract:

Introduction: One of the most important steps in cataract surgery is the development of a continuous curvilinear capsulorrhexis (CCC) in the anterior capsule and in mature cataract patients due to absence of red reflex, it is challenging to determine the spreading edge of the capsulorrhexis. In such cases, to perform CCC, anterior capsule is stained briefly with any vital dye like trypan blue. So this study was conducted to see the effectiveness and safety of trypan blue dye and to observe outcomes of small incision cataract surgery (SICS) in mature cataracts.

Material and Method: The present study was a prospective cohort study conducted on 100 patients having mature senile cataract in single eye with age from 50-70yrs posted for SICS Detailed demographic and clinical history of the subjects was taken. Preoperative, intraoperative and postoperative evaluation was done and findings like uncorrected visual acuity (UCVA) & best corrected visual acuity (BCVA), slit lamp, fundus, intra-ocular pressure (IOP), keratometry, B-scan etc. findings were noted and analyzed using SPSS version 20.

Result: The present study showed mean age of 60.99+5.97years. The study depicted female dominance and 96% of the patients had mature cataract. 10% had corneal edema without any increase in IOP and all patients responded well to the treatment. In 95% cases, easily and safely complete CCC was performed. No significant variation was seen in IOP during follow up visits. The final visual outcome was satisfactory with 90% achieving UCVA of 6/12 or better and 95% attaining BCVA of 6/12 or better.

Conclusion: Our study has shown that the use of trypan blue as an adjunct to SICS is a safe and effective approach, which simplifies capsulorrhexis in mature cataract patients, as it has a low incidence of intraoperative problems and easily treated postoperative difficulties.

Keywords: Trypan Blue, Mature Cataract, CCC, Capsulorrhexis etc.

Introduction

A cataract is an intense clouding of the normally clear lens of the eye that gradually impairs vision as the condition worsens. It is estimated that between 50 and 80 percent of India's 12.5 million blind people are blind due to cataract.[1,2] The incidence of cataract is 0.4-0.5%, according to the 'National Programme for Control of Blindness (NPCB)'; hence, there are 61.5lakhs new cases of cataracts that require surgery annually.[3] In developing nations like India, where a sizable portion of the population lives in rural regions, the delayed presentation of cataract when it reaches the advanced stages like mature cataracts occurs due to a combination of reasons like illiteracy and lack of awareness, which ultimately results in delayed treatment of the cataract. Mature cataract is when the entire cortex, from the capsule to the nucleus, turns white and opaque.[4] According to a research in a rural area, the frequency of mature cataract was found to be 57% of all cataracts.[5] The bulk of individuals with visually significant cataract are unable to pay for currently available sophisticated and costly cataract surgical methods. It has been found that small incision cataract surgery (SICS) is a safe and efficient kind of cataract surgery, making it an affordable treatment.[6] One of the most important steps in cataract surgery is the development of a continuous curvilinear capsulorrhexis (CCC) in the anterior capsule, which makes the bag intraocular lens (IOL) placement easier. When under stress during surgery, a tear with non-continuous components is likely to develop radial extensions.[7] In order to make sure that the tear is continuous, it is crucial to visualize the capsule flap while it is being formed. When executing capsulorrhexis, the red fundus

reflex caused by the coaxial light of the microscope is crucial for visualizing the capsule. In the case of mature and hypermature cataracts due to absence of red reflex, this retroillumination is lacking, and therefore, it is challenging to determine the spreading edge of the capsulorrhexis.[8-10]

Several techniques have been described in the literature to visualize the outline of the capsulorhexis during surgery. However many of them are time consuming and require pre-operative preparation except ocular tissue staining. So in case of mature cataracts, staining the anterior capsule briefly with any vital dye e.g. trypan blue, methylene blue and gentian violet is considered to be one of the most efficient and time saving method to easily see during capsulorrhexis. Methylene blue and gentian violet stains are linked to corneal edema that results from endothelium damage. While trypan blue, even prior to corneal transplantation, is frequently used to count and assess the endothelial cell layer in donor corneoscleral buttons.[11] A prospective study has found SICS to be a safe and efficacious alternative for mature cataracts especially when performed using trypan blue dye.[12] So in our study to perform capsulorhexis, as an adjunct the staining of anterior capsule with trypan blue was done to see the effectiveness and safety of trypan blue dye and outcomes of SICS in mature cataracts.

Material and Method:

This study was a prospective cohort study conducted on mature cataract patients posted for SICS at Ophthalmology Department at GMERS Hospital and Medical college, Valsad, Gujarat from November 2020 to April 2022. A total of 100 patients having mature senile cataract in single eye with age from 50-70yrs were included in the study. Patients not willing to participate and having immature, traumatic or complicated cataract, corneal opacities, congenital abnormalities of eye, corneal dystrophy and degeneration, signs of pervious uveitis and retinal disorders seen on B-scan were excluded from the study.

Ethical clearance was obtained from 'Institutes Ethics Committee' and full informed written consent was taken from participants after explaining procedure in their local language. Detailed demographic and clinical history of the subjects was taken. Preoperative evaluation of each patient was done. Patients visual acuity & best corrected visual acuity (BCVA), slit lamp examination for ocular adnexa & anterior segment was performed. Intra-ocular pressure by non-contact tonometry was noted. B-scan to rule out any posterior segment pathology, keratometry and IOL power calculation was done. Preoperative dilatation was done using 0.8% tropicamide + 5% phenylephrine eye drops. For surgery, peri-bulbar block anesthesia was given to the patients and then the eye was prepared, painted, and draped; an eyelid speculum was applied. Superior rectus bridle suture was taken with 3-0 silk suture as given and fixed to superior part of the drape. Limbal based conjunctival flap was used to expose the sclera for superior tunnel incision. Hemostasis was achieved with wet field cautery. Scleral straight incision was made with 15no. bard parker knife, 2mm from limbus. Sclera-corneal tunnel was made with crescent blade, extended up to 1mm into clear cornea. Sideport entry was made with 15-degree lance tip knife. Air bubble was injected in anterior chamber followed by anterior capsular staining by 0.1ml of 0.1% trypan blue and after 5-10 seconds balanced salt solutions was irrigated to wash out excess dye. Ophthalmic viscosurgical device (OVD) was filled in anterior chamber (AC) and then CCC was performed with cystitome made up of 26 gauze needle mounted on 2cc syringe through side port. A 3.2mm keratome was used for anterior chamber entry, incision was enlarged a bit, such that internal cornea lip was kept 25% larger than external incision. Hydro dissection and hydro delineation was performed with 27gauze cannula mounted on 5cc syringe filled with balanced salt solution. Nucleus was rotated and prolapsed into anterior chamber and was delivered with the help of wire vectis (Snellen lens loop). Residual cortex was removed using Simco's two-way irrigation aspiration cannula. Ophthalmic viscosurgical device (OVD) was injected in AC. Posterior chamber intraocular lens (PCIOL) was implanted in capsular bag with the help of McPherson's forceps and dialed into bag by sinskey hook. Anterior chamber wash was given by simco's irrigation and aspiration cannula and AC was formed with BSS and side port was hydrated. Integrity of scleral incision was checked. Sub-conjunctival injection of gentamicin and dexamethasone was given in conjunctival flap to cover incision. Eye was padded and patched. During surgery, anterior capsular staining was observed and noted. Completion of CCC, Pupillary miosis was observed and any adverse reaction if seen was listed and elaborated. Follow up evaluation was done on day1, day7, and end of 1st month. Antibiotic-steroid drops were started 1hourly and then tapered in around 3-4 weeks. Oral antibiotic and NSAIDS for 5days were given. Visual acuity with best corrected visual acuity, slit lamp bio microscopy and tonometry was done and findings were noted and treated accordingly. Fundus examination was done at each follow up. All the data was noted and analyzed using SPSS version 20. A p-value <0.05 was considered as significant.

Result:

All the 100 subjects with mature cataract who underwent SICS were evaluated preoperatively,

intraoperatively, postoperatively. All the data including 1 month of follow up were recorded. The study included patients between 50-70years of age, with mean age of 60.99+5.97years.

As visible from table 1, 96% of the patients had mature cataract followed by hypermature in 3% and intumescent cataract in 1% of study population. Participants were divided into 4 age groups i.e. 50-55years, 56-60years, 61-65years and 66-70years with 27%, 28%, 20% and 25% patients respectively.

In present study 84% of the patients had no systemic illness and the rest participants had hypertension, diabetes mellitus and ischemic heart disease seen in 7%, 6% and 3% patients respectively.

Table 1: Distribution of patients based on demographic and clinical findings

Variable		n (%)
Type of cataract	Mature	96 (96%)
	Hypermature	3 (3%)
	Intumescent	1 (1%)
Age in years	50-55	27 (27%)
	56-60	28 (28%)
	61-65	20 (20%)
	66-70	25 (25%)
Systemic illness	Hypertension	7 (7%)
	Diabetes mellitus	6 (6%)
	Ischemic heart disease	3 (3%)
	Nil	84 (84%)
Slit lamp findings	Mild to moderate corneal edema	8 (8%)
	Striate keratopathy	2 (2%)
	Anterior chamber reaction	5 (5%)
	Inflammatory membrane	3 (3%)
Fundus findings	Age related macular degeneration	2 (2%)
	Non proliferative diabetic retinopathy	1 (1%)
	Optic atrophy	2 (2%)

The study showed dominance of females with 64% and rest 34% were males as seen in figure 1.

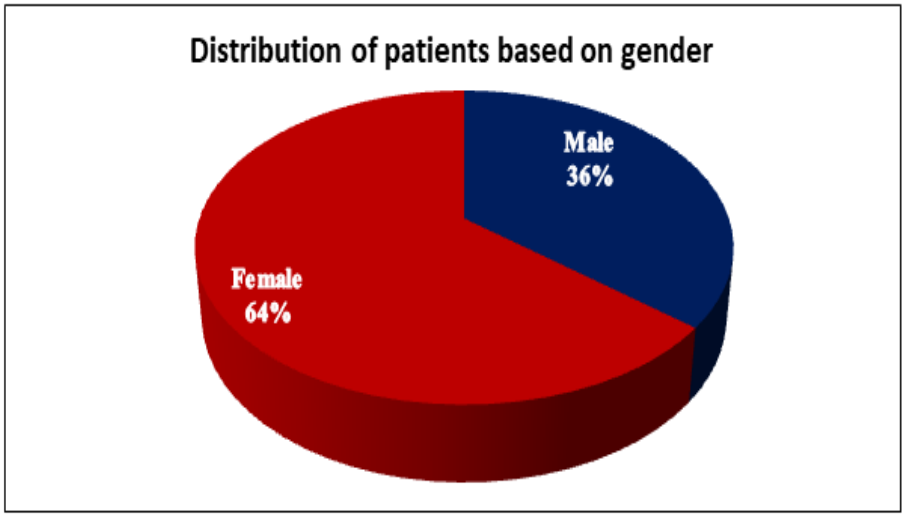

Figure 1: Distribution of patients based on gender

Table 1 depicts the split lamp and fundus findings of the participants. Endophthalmitis was not seen in any of the patient. 10(10%) patients of our study had corneal edema, out of which 8(8%) had mild to moderate from of corneal edema and 2(%) had striate keratopathy. All the 10(10%) corneal edema patients were treated intensively with oral and topical steroids and all responded well to the treatment except one striate keratopathy and one mild to moderate corneal edema patient, as they developed corneal decompensation. However, the striate keratopathy patient who responded well had optic atrophy on fundus examination. The corneal edema was not associated with an increase IOP. 5(5%) patients had AC reaction and 3(3%) patients had postoperative inflammatory membrane, all of

them responded well to the medication and the condition was resolved within a week. As far as fundus findings are concerned, 2(2%) subjects showed age related macular degeneration (ARMD), 1(1%) had non-proliferative diabetic retinopathy (NPDR) and 2(2%) patients showed and optic atrophy.

Table 2 illustrates intraoperative findings in the study population. In all the patients, due to effective and adequate staining of anterior capsule by trypan blue, a good contrast between lens and capsule was observed which helped in performing better CCC. In 95(95%) patients, safely and with ease, complete CCC could be performed thus preventing any complications.

In rest 5(5%) patients CCC was incomplete, so capsulotomy by can-opener method was performed. Pupillary miosis was observed in about 7(7%) cases of which 4 patients were associated with incomplete CCC. Miosis of pupil hinders performing proper CCC.

Table 2: Intraoperative findings in the study population

Intraoperative findings	n (%)	Intervention
Complete CCC	95 (95%)	---------
Incomplete CCC	5 (5%)	Can opener capsulotomy
Pupillary miosis	7 (7%)	Intracameral inj. Epitrate (Adrenaline1:1000)
Both Incomplete CCC and Pupillary miosis	4 (4%)	---------

As clear from figure 2, post operatively at day 1, the uncorrected visual acuity (UCVA) of 6/12 to 6/6 was observed in 25(25%) patients, 6/24 to 6/18 in 40(40%) patients, 6/60 to 6/36 in 20(20%) patients and <6/60 in 15(15%) patients. Postoperatively at day 7, the UCVA of 6/12 to 6/6 was seen in 55(55%) patients, 6/24 to 6/18 in 35(35%) patients, 6/60 to 6/36 in 4(4%) patients and <6/60 in 6(6%) patients. Postoperatively at 1-month, the UCVA of 6\12 to 6/6 was noted in 90(90%) patients, 6/24 to 6/18 in 5(5%) patients, 6/60 to 6/36 in 1(1%) patients and <6/60 in 4(4%) patients.

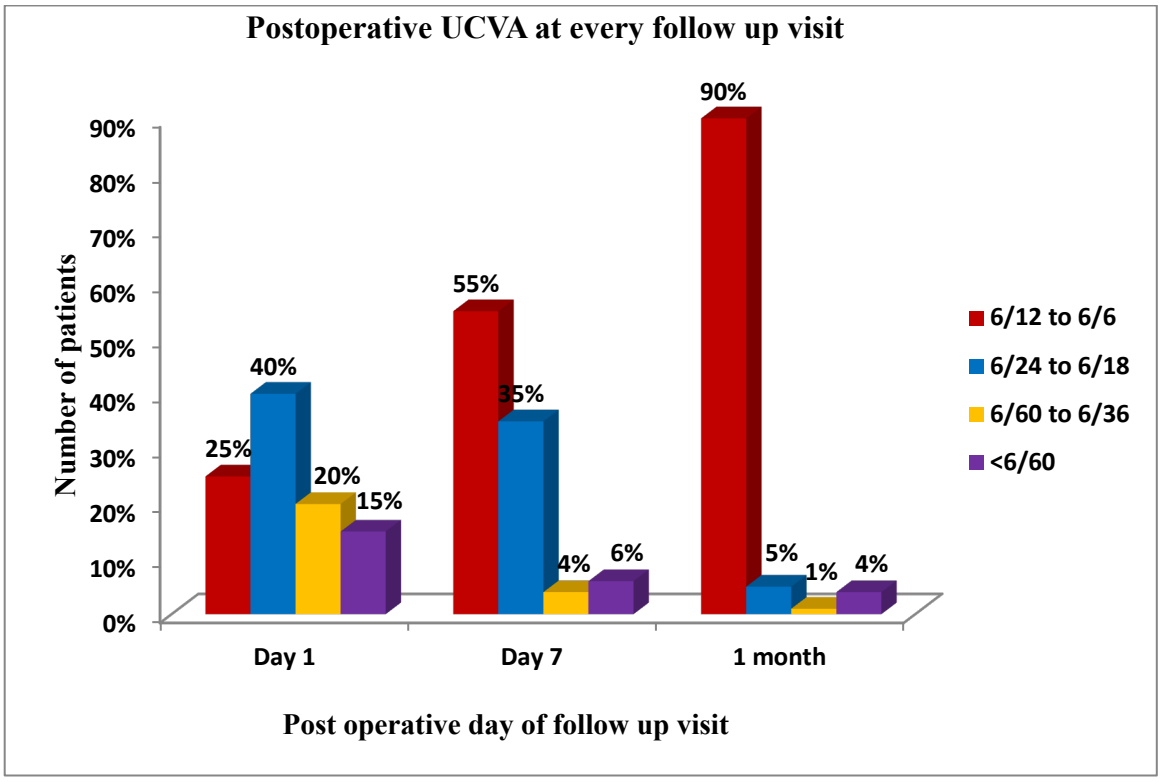

Figure 2: Postoperative UCVA at every follow up visit

Figure 3 illustrates the IOP of the participants. IOP was measured by NCT (non-contact tonometry) at all the visits i.e. at day 1, day 7 and 1month. No significant variation was observed and all the readings were within normal range.

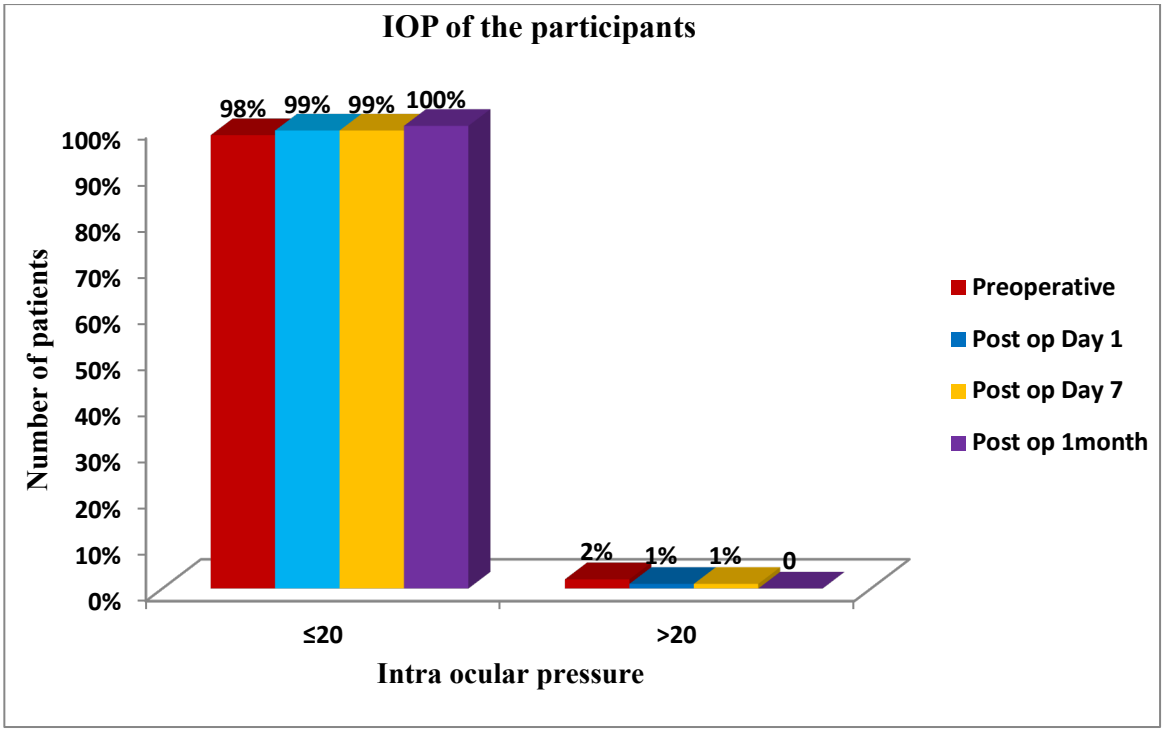

Figure 3: IOP of the participants

Discussion

The present study was conducted on 100 mature cataract patients to see the effectiveness and safety of trypan blue dye and outcomes of SICS in mature cataracts. The opening of the anterior lens capsule during cataract surgery is one of the most important procedures because an uncontrolled "capsulorhexis" can lead to a many complications. The use of a vital dye has become a standard procedure to better visualize the lens capsule; anionic (acidic) dyes, such as "trypan blue," are less harmful to ocular tissue than cationic (basic) dyes.[13]

The trypan dye is most efficient at comparatively low concentrations, is not likely to be source of any toxicity, and is recognized for its biocompatibility with the intraocular structures and corneal endothelium. Additionally, the surplus dye can be washed out quickly after being applied to the lens capsule. So in present study 0.1% trypan blue was used as an adjunct to perform capsulorhexis in mature cataract patients.

The mean age of patients in current study was 60.99+5.97years, which is strongly supported by the study of Rajni Gupta et al.[14] as they had mean age of 61.3 ±9.2 years. Our study showed female dominance and majority of patients were from age group 56-60years followed by 50-55years. These findings are in concordance with the study by Vidhya Verma[15] and in contrast with the study by Anitha S. Maiya et al.[16] as their research showed male predominance and had majority of patients were from the age group of 60-69years. The present study had 96% patients of mature cataract which is in harmony with the study by Anitha S. Maiya et al.[16] and Vidhya Verma [15] as they also had maximum of mature cataract patients although percentage was much lower than our study.

In our study, no significant variation was observed in IOP of the patients during follow up visits and all the readings were within normal range. The final visual outcome in our study was satisfactory with 90% achieving UCVA of 6/12 or better and 95% attaining BCVA of 6/12 or better. Our study showed 95% success rate of CCC by use of trypan blue dye.

In all the cases, due to effective and adequate staining of anterior capsule by trypan blue, a good contrast between lens and capsule was observed which helped in performing better CCC. This outcome is strongly in agreement with the study by Melles et al.[17] as in mature cataract patients due to use of trypan blue, they also observed complete CCC uneventfully in all the patients with no residual staining, quiet AC, normal IOP and no endothelial damage.

Our study also observed that a uniform large single air bubble is essential for staining of the anterior capsule. Melles et al.[18] advocated the use of an air bubble in anterior chamber with the injection of dye between the air bubble and the anterior capsule to prevent its dilution. Study by Horiguchi et al.[19] is also in support of our findings as they showed high success rate of CCC completion with trypan blue dye & ICG with no elevation in IOP,

endothelial cell damage, and postoperative inflammation. However in our study 5% cases had postoperative AC reaction, although all were resolved by day seven with medication. In present study, corneal edema was observed in 10% patients, although it was not associated with an increase IOP. Endophthalmitis was not seen in any of the patient and intraoperatively, 7% had papillary miosis and 5% had incomplete CCC. A similar study conducted by Soosan Jacob et al. [20] is in harmony with our findings.

They completed CCC uneventfully in 96.15% cases, 3.85%, 3.80%, 5.75%, 9.6%, 96.16% had incomplete CCC, papillary miosis, postoperative corneal edema, AC reaction, and BCVA of 20/30 or better respectively. Our result is strongly supported by Kothari K. Jain et al.[10], as they demonstrated efficacy and safety of 0.1% trypan blue and concluded capsular staining with trypan blue to be a very useful and safe technique that simplifies capsulorhexis in mature and hypermature cataract. Our study is also in concordance with the study by V.D. Karthigeyan et al.[13], as by using trypan blue, they revealed good visibility of the capsular flap and completion of capsulorhexis in cataract without red reflex, however they used 0.025% trypan blue.

Conclusion

Our study has shown that the use of trypan blue as an adjunct to SICS is a safe and effective approach, which simplifies capsulorrhexis in mature cataract patients, as it has a low incidence of intraoperative problems and easily treated postoperative difficulties. Trypan blue stains anterior capsule, improving cortical clean-up, IOL implantation, and capsulorhexis by increasing its visibility. Trypan blue increases success rate of mature cataracts as it helps to achieve a capsulorhexis that is precisely centered and overlays the IOL optic to prevent capsular phimosis.

Sufficient staining can be achieved with a tiny amount of dye at a relatively low concentration, and there are no negative side effects like vitreous leakage, endothelium staining or toxicity, or raised IOP. Moreover, the method is inexpensive and produces good postoperative visual results. Capsular staining may also be used in the education of novice surgeons, as enhanced flap visibility could aid in controlling the advancement of the cataract even in cases when the patient has a strong red reflex.

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