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Original Research Article

Prevalence of postoperative complications in manual small-incision cataract surgery patients and its association with risk factors: a prospective cohort study in a tertiary eye care hospital

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ABSTRACT

Background: This study aimed to determine the prevalence of postoperative complications in patients undergoing Manual Small Incision Cataract Surgery (MSICS) and to assess the associations of these complications with risk factors such as age, high myopia, and diabetes mellitus. This research sought to identify the most common postoperative complications and evaluate the prevalence of blindness due to these complications.
Methods: A prospective cohort study was conducted in GMCH Srikakulam over two months. The study included 100 patients who had undergone MSICS for senile cataracts. Patients were evaluated postoperatively for complications, and the presence of risk factors was recorded. Statistical analysis was performed using SPSS and SAS software, employing a multivariate regression model to identify significant associations between risk factors and complications.
Results: Out of 100 patients, 44 experienced postoperative complications. The most common complication was corneal edema, and no cases of blindness were reported. Age was found to be significantly associated with corneal edema, striate keratopathy, and posterior capsular opacity (PCO), while diabetes mellitus and high myopia were not significantly associated with the complications observed.
Conclusions: The study concluded that corneal edema is the most prevalent postoperative complication following MSICS, with older age being a significant risk factor. Improved surgical techniques and better training could reduce these complications. However, additional studies with larger sample sizes are needed to better understand the impact of diabetes mellitus and high myopia on postoperative outcomes.

Keywords: Fetal distress, Hypertension in pregnancy, Stillbirths

INTRODUCTION

The National Program for Control of Blindness (NPCB) was initially introduced in India in 1976 with the aim of lowering the blindness rate to 0.3% by 2020.[1] It was further updated by the guidelines from the VISION 2020 and Universal Eye Health: Global Action Plan 2014-2019.[1] To determine the status of eye health in the country, National Blindness and visual impairment survey 2015-2019 were conducted using the RAAB-6 methodology.[1] The observations that were made in the survey are as follows:[1]

The prevalence of blindness in the population aged 50 years and older was 1.99%.

Among people aged >50 years, cataracts were found to be responsible for 66.2% of the blindness cases.

Furthermore, the data revealed an increased proportion of blindness caused by complications from cataract surgery, which now stands at 7.2%.

Participants in the study were considered blind if their visual acuity in the better eye, even with correction, was less than 3/60. From the above data, it can be inferred that the burden of cataracts is increasing in the health system of the country when the new case load is added by complications due to cataract surgery. With respect to cataract surgery, while both phacoemulsification and manual SICSs yield excellent visual outcomes, SICSs are much faster and more cost-effective than traditional SICSs and require less advanced technology, making them more suitable for use in developing countries. In India, manual SICS has become a widely adopted cataract surgery method and is commonly chosen as an alternative tophacoemulsification.[2,3]

This necessitates investigation of the various postoperative complications associated with the manual SICS method. Manual SICS is a reliable and effective procedure that provides rapid visual recovery, and any procedure inherently has certain limitations that can lead to postoperative complications.[4] Postoperative complications, which are generally encountered, were also reported.[5]

While mentioning the risk factors that can be associated with the occurrence of postoperative complications, age and high myopia are strongly associated with postoperative complications.[6] Patients who had no evidence of diabetic retinopathy preoperatively had a favorable visual prognosis, similar to that of patients without diabetes.[7] This study will be used to validate the above information.

Review of the literature

Cataracts remain a leading cause of blindness in India. The decrease in surgeries in the last 2 years has led to a further increase in backlog, which demands more efficient procedures with fewer complications. MSICS plays a crucial role in addressing cataract-related blindness in developing nations. However, as a variant of ECCE (extracapsular cataract extraction), it is also associated with postoperative complications. Visual recovery after surgery is poor in 25% of patients, and the presence of postoperative complications also contributes to this recovery.[8]

The different steps taken while performing MSICS can affect the incidence of various postoperative complications that need to be addressed after surgery. Corneal edema and striate keratopathy are observed due to the increase in intracameral maneuvers while delivering nuclei. Descemet's membrane detachment is observed during faulty entry into the anterior chamber or forcible pushing of an IOL. Hyphemia is caused by increased manipulation of the iris root and trauma caused by either premature entry or haptic-induced chaffing of the uvea. Iritis and Iridodialysis are seen when there is difficult delivery of the nucleus (due to undilated pupil) and trauma to the iris base. The occurrence of endophthalmitis as a complication depends on the length of the scleral corneal tunnel, the use of prophylactic antibiotics in the eye care setting and the presence of iris prolapse.[9]

A flat chamber with wound leakage is observed in cases of improper wound integrity. The prevalence of cystoid macular edema is greater in cases where there is a larger incision size (due to greater chances of blood–retinal barrier disruption) and increased iris manipulation. Decentration of the IOL is more common when an opener or V-shaped capsulorrhexis method is employed.[10] Vitreosity in the anterior chamber is observed when the posterior capsular rent is observed as an intraoperative complication. Although MSICS requires a high level of skill and patience from surgeons, it is still a safe, effective, and economical procedure. Modern cataract surgery is effective for highly myopic cataract patients. Precautionary measures and regular follow-ups decrease the incidence of intraoperative and postoperative complications such as retinal detachment, CSME, clinically significant macular edema and decentration of the IOL.[11] Older age is a risk factor for complications, including postoperative infections and corneal problems, in cataract surgery.[12,13]

Individuals with diabetes have a 2- to 5-fold increased risk of developing cataracts, typically at an earlier age. Approximately 20% of cataract surgeries are conducted on patients with diabetes. While some studies suggest that such surgeries can accelerate diabetic retinopathy and vitreous hemorrhage and result in vision loss, other research shows that improvements in preoperative retinopathy management, advancements in surgical techniques, and better glycemic control can lead to fewer complications and better visual outcomes.[14]

Aims and objectives

To determine the prevalence of various postoperative complications in MSICS patients.

To determine the prevalence of blindness due to various postoperative complications.

The aim of this study was to assess the associations of risk factors (age, high myopia and diabetes) with postoperative complications.

The most common postoperative complications were determined.

The following hypotheses are also tested: (a) Is diabetes mellitus associated with any postoperative complications in patients who undergo MSICS? (b) Is older age linked to any postoperative complications in patients who have MSICS? (c) Does high myopia contribute to any postoperative complications in patients who undergo MSICS?

METHODS

Approval from the institutional ethics committee was obtained before beginning the study.

A prospective cohort study was conducted at a GMCH Srikakulam in southern India for two months from August 2024 to October 2024. The study population included post-MSICS patients with senile cataracts.

A purposive nonprobability sampling method was used to determine the sample size, and 100 patients were selected based on specific inclusion and exclusion criteria.

Inclusion criteria

All post-MSICS patients with senile cataracts provided consent. Patients aged more than 45 years. There was no previous ocular comorbidity.

Exclusion criteria

Individuals who did not consent. Individuals showing inadequate visual progress.

Prior to the evaluation, the patient was provided with information about the study and provided consent.

Patients were evaluated on the postoperative day and during routine follow-up in the OPD for the presence of any complications.

A case study form was used to fill out the ocular examination details and obtain a detailed history from the patient.

The following instruments were used during the evaluation of the patients:

Visual acuity (both preoperative and postoperative) was measured with the help of Snellen's charts and the AR (augmented reality) and SV images. Slit lamp biomicroscopy was used to observe the cornea, anterior chamber, pupil, lens, and fundus. Ophthalmoscopy was used for fundus examination. A B-scan was used when the fundus was not visualized. A noncontact tonometer was used for IOP measurements. A gonioscope was used for evaluating the angle of the anterior chamber. Phenylephrine (5%) was used as a mydriatic during the procedure. Blood sugar level testing was performed if diabetes mellitus was present.

All the postoperative complications noted were noted, as was the presence of any of the considered risk factors (DM, high myopia, age).

Details about all the patients (including name, age, sex, DM status, high myopia status and any postoperative complications) were downloaded into the Excel sheet and analyzed. The age of the patients was divided into two groups for analysis: (i) 1st group: 45-60 years, (ii) 2nd group: 61-75 years.

All the statistical analyses were performed using SPSS software and SAS software version 9.4. The prevalence of all the postoperative complications is presented in the bar graph. The frequency of each complication associated with the considered risk factors is also shown in the distribution bar plot. A multivariate regression model was used for categorical raw data to determine whether there was a significant association between risk factors and complications. A p value is considered to indicate statistical significance at the 5% level.

RESULTS

A total of 100 patients were included in the study, of whom 44 developed postoperative complications. Among these, 45 patients were in the age group of 45–60 years, while 55 patients were between 61–75 years of age. High myopia was present in 9 patients, and among them, 5 experienced postoperative complications. Diabetes mellitus was documented in 30 patients, 11 of whom developed complications.

The most commonly observed postoperative complication was corneal edema. Importantly, no cases of postoperative blindness (defined as visual acuity <3/60) were reported in the study cohort. Additionally, complications such as bullous keratopathy, hypopyon or toxic anterior segment syndrome (TASS), epithelial growth, fibrous growth, and endophthalmitis were not observed in any of the patients.

Corneal edema was seen more frequently in older patients, indicating a possible age-related vulnerability to this complication (Figure 1).

Although some patients with diabetes mellitus also developed corneal edema, statistical analysis did not reveal a significant association (Figure 2). Striate keratopathy was another common complication, occurring more frequently in the older age group (Figure 3). It was also observed in a few patients with high myopia and diabetes mellitus (Figures 4 and 5), although these associations were not statistically significant.

Descemet's membrane detachment (DMD) was noted in some patients, with a higher frequency among the older age group (Figure 6). A few cases were also reported in patients with high myopia and diabetes mellitus (Figures 7 and 8). Hyphema was observed only in a limited number of older individuals (Figure 9).

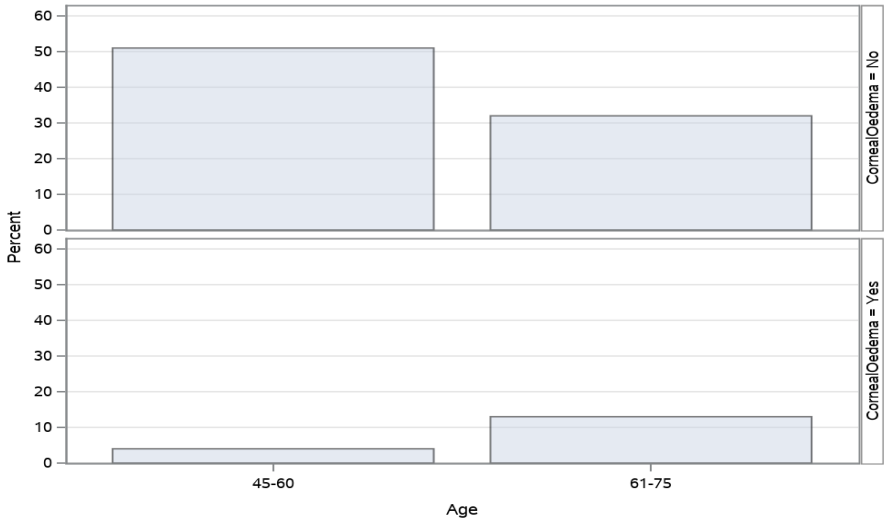

Figure 1: Distribution of corneal oedema by age.

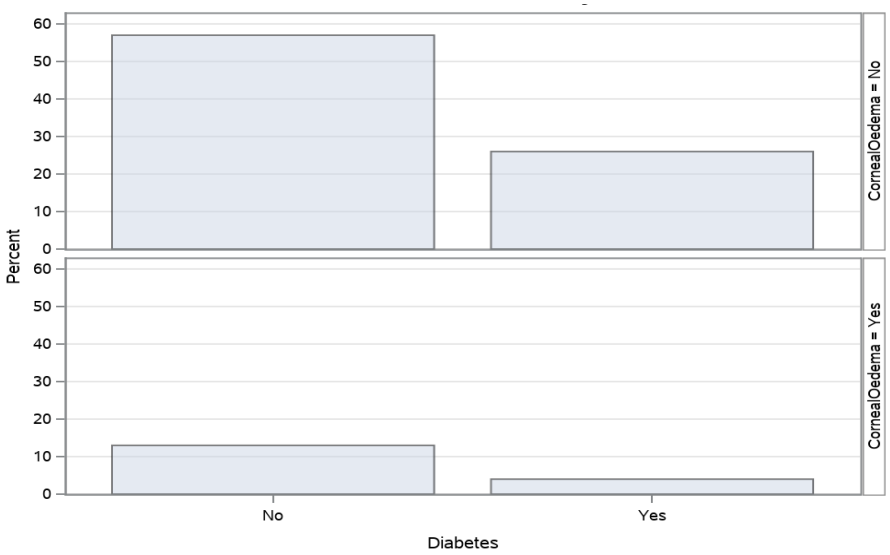

Figure 2: Distribution of corneal oedema by diabetes.

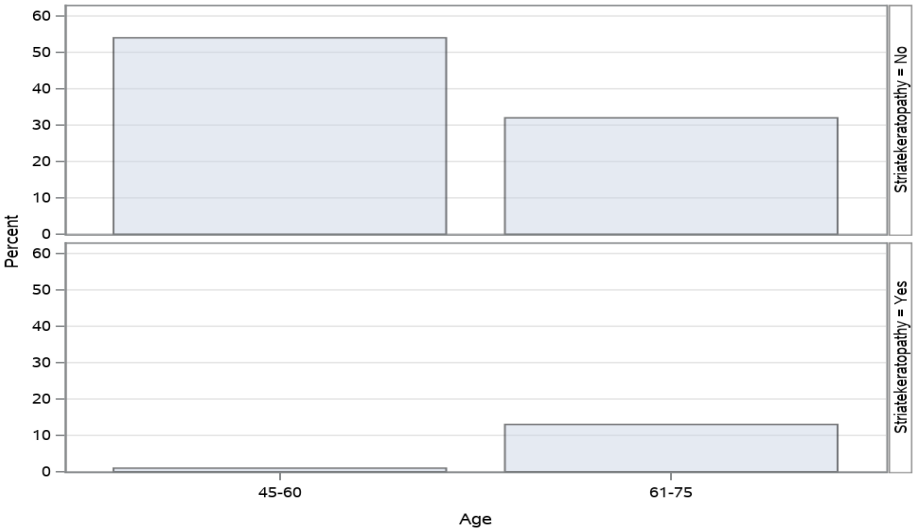

Figure 3: Distribution of striate keratopathy by age.

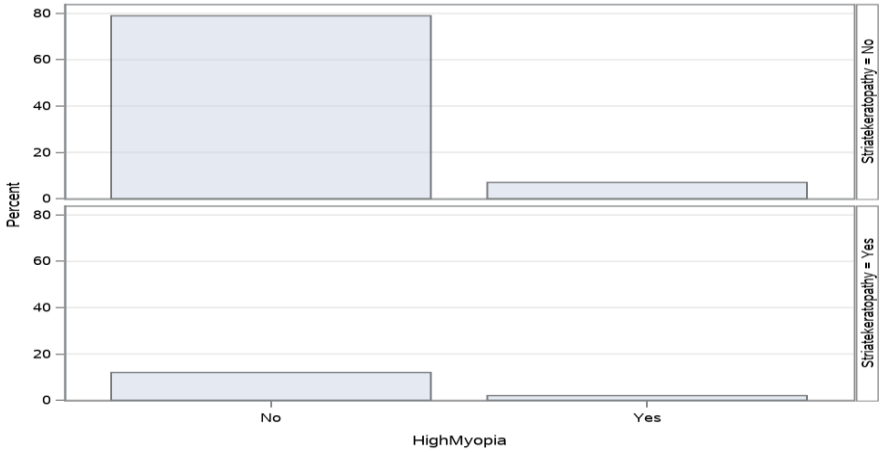

Figure 4: Distribution of striate keratopathy by high myopia.

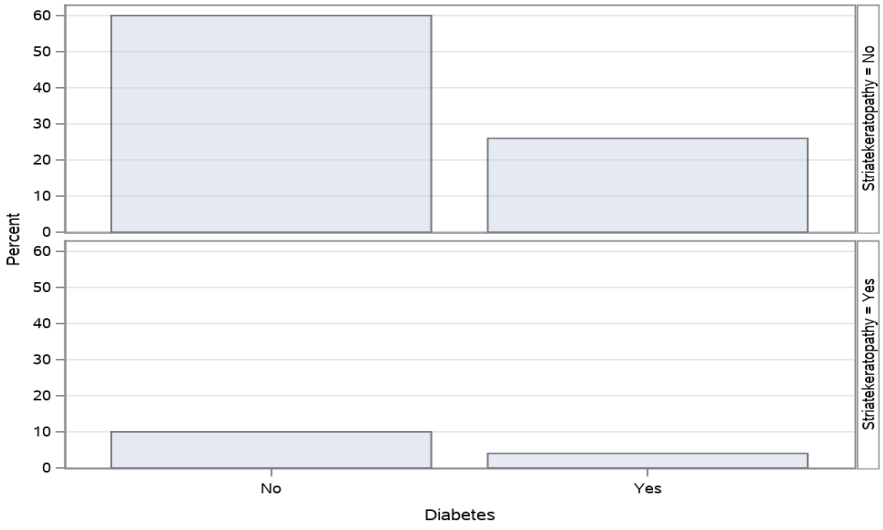

Figure 5: Distribution of striate keratopathy by diabetes mellitus.

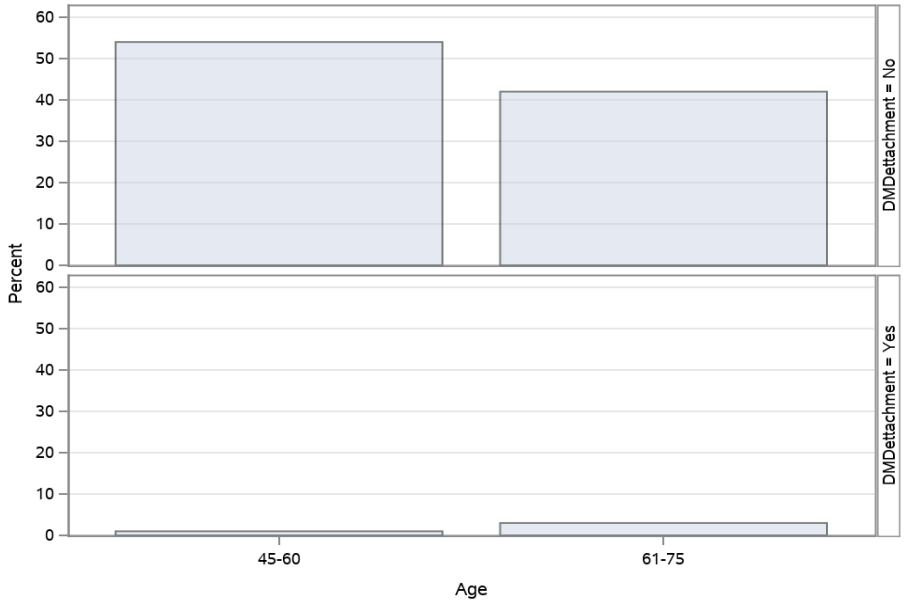

Figure 6: Distribution of descemet's membrane detachment by age.

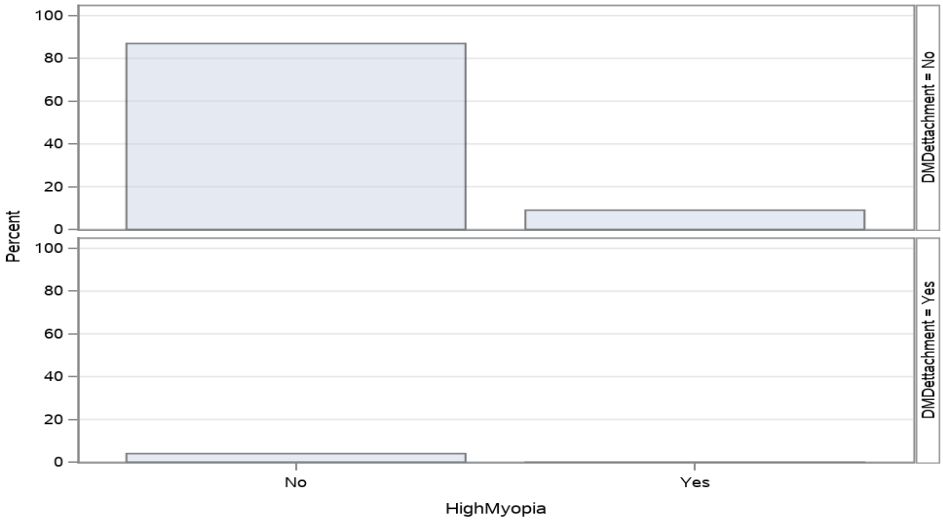

Figure 7: Distribution of descemet's membrane detachment by high myopia.

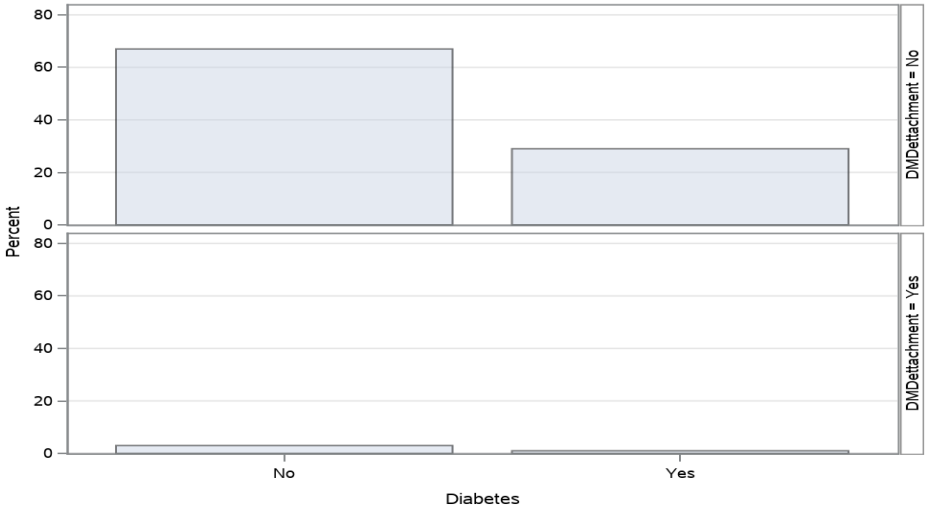

Figure 8: Distribution of descemet's membrane detachment by diabetes mellitus.

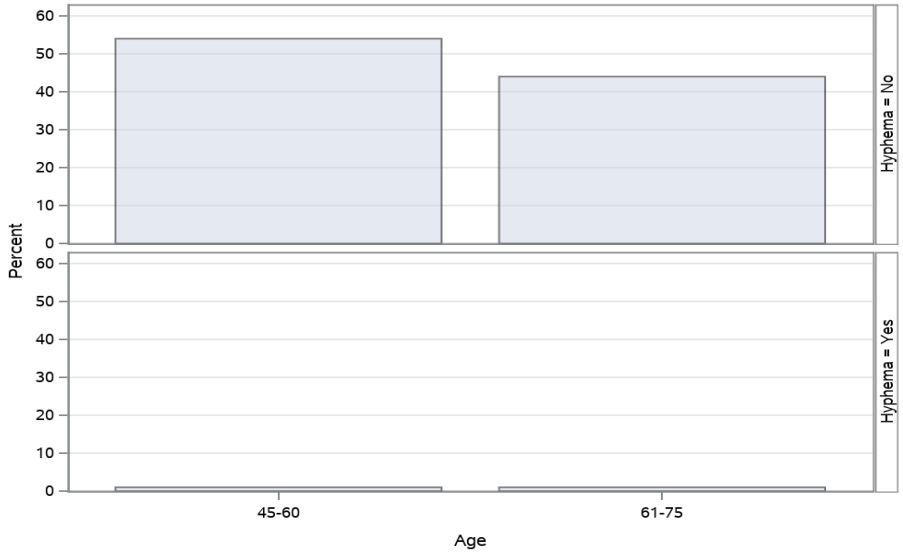

Figure 9: Distribution of hyphema by age.

DISCUSSION

MSICS is a manual procedure; the outcome of the surgery highly depends on the surgical skill. The most important step is the delivery of the nucleus and the intracameral maneuvers associated with it; therefore, the most common complication is also expected to arise at this step, which are corneal complications. This study revealed corneal edema to be the most common complication.

Since MSICS is a very safe and effective procedure with a very low incidence of blindness, no cases of blindness (visual acuity <3/60) were observed. The incidence of blindness further decreases with routine follow-up. However, in one patient, moderate visual acuity (6/18-6/60) was observed, and retinal detachment, vitreous hemorrhage and cystoid macular edema were observed as complications.

The p values obtained from the statistical analysis suggest the following: 1) Corneal edema, striate keratopathy and PCO were significantly different at the 5% level of significance, with age as a risk factor. Therefore, old age can be considered a risk factor for several postoperative complications, and this hypothesis is supported. This can be explained by the fact that with increasing age, the hardness of cataract increases and therefore increases the chances of complications. This finding also correlates with the findings of a previous study.[12] 2) Diabetes mellitus was not significantly associated with any of the considered postoperative complications. Therefore, the hypothesis that DM is a risk factor was rejected in this study, and this finding is consistent with the relationships observed during the review of the literature.[13] This could be because this study excluded patients with underguarded visual progress and because of better preoperative management of diabetes. A change in the experimental design to a different study setup may bring forth new results. 3) High myopia, a risk factor, was also not found to be a statistically significant risk factor in this study. This may be due to the small sample size and good expertise of the surgeon, which prevented intraoperative complications, and regular follow-up, which eliminated postoperative complications. However, an observation of the raw data indicates that high myopia is associated with increased cases of IOL decentration.[11] Therefore, a decision with confidence cannot be made regarding the hypothesis that high myopia is a risk factor. This requires further research.

Limitations

Despite the strengths of this study, several limitations should be acknowledged. First, the sample size was relatively small, which may limit the generalizability of the findings. Second, this was a single-center study, and therefore, results may not be representative of broader populations or different clinical settings. Third, the cross-sectional design prevents establishing causal relationships. Lastly, potential confounding variables may not have been entirely accounted for, which could influence the interpretation of results.

CONCLUSION

Although corneal edema is a common complication, it can be treated easily. This can be avoided by improving surgical techniques and training surgeons. Age was found to be significantly correlated with corneal complications. Therefore, the age at which surgery should be performed to avoid such complications is an important factor in visual outcome. Additionally, improved surgical techniques involving decreased intracameral maneuvers and avoiding viscoelastic placement between the nucleus and cornea may help reduce complications. In old, aged individuals, to avoid the complications of PCO, good cortex aspiration, capsule polishing and improved material and IOL design can be used. This study also invites further research to explore the association between diabetes and high myopia risk as risk factors with a different experimental design and increased sample size to determine whether there is any variation in the results. This study identified corneal edema as the most prevalent postoperative complication following Manual Small Incision Cataract Surgery (MSICS), with a significant association between older age and increased risk of complications such as corneal edema, striate keratopathy, and posterior capsular opacity (PCO). Neither diabetes mellitus nor high myopia demonstrated a statistically significant association with postoperative complications in this cohort. No cases of blindness were reported, highlighting the safety of MSICS. Further research with larger sample sizes is warranted to explore the impact of diabetes and high myopia on postoperative outcomes.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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