

Impact of continuing anti-platelet drugs during manual small incision cataract surgery under subtenon's anesthesia in tertiary care in South India



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ABSTRACT

Background: Antiplatelet drugs are routinely used in elderly patients with atherosclerotic diseases to prevent cardiovascular ischemic events such as acute coronary syndrome, myocardial infarction, or stroke. While various studies have established the safety of continuing anti-platelet drugs during phacoemulsification. Hence, the current study was undertaken. **Aims and Objectives:** To observe the impact of continuing anti-platelet drugs during manual small incision cataract surgery (MSICS) under subtenon's anesthesia in tertiary care in South India. **Materials and Methods:** Patients undergoing small incision cataract surgery in a medical college in South India from August 2024 to December 2024 were part of the study after obtaining written informed consent. They were randomly assigned to two groups. Group 1-patients taking antiplatelet drugs for a thromboembolic disorder and Group 2-patients not on antiplatelets drugs. MSICS was performed under subtenon's anesthesia using a blunt cannula (no sharp needle prick). Patients were monitored intraoperatively, postoperatively on day 1, day 7, and 30 for any ocular hemorrhage and thromboembolic events. **Results:** Incidence of hemorrhagic complications was 46% in group 1 and 26% in the control group on the first post-operative day. The subconjunctival hemorrhages resolved spontaneously, and there was no difference between the two groups at the end of 1 month post-surgery. There was also no difference in the final best-corrected visual acuity between the two groups. The hemorrhages that occurred were self-limiting and visually insignificant. No patient had a retrobulbar, vitreous, choroidal hemorrhage, or a sight-threatening complication. No thromboembolic events were noted in the 1-month post-operative period. **Conclusion:** The present study results explain that it is safe to continue antiplatelets in MSICS performed under subtenon anesthesia by an experienced surgeon.

Key words: Antiplatelets; Manual small incision cataract surgery; Subtenon's anesthesia; Subconjunctival hemorrhage; Postoperative vision

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INTRODUCTION

Antiplatelet drugs are routinely used in elderly patients with atherosclerotic diseases to prevent cardiovascular ischemic events such as acute coronary syndrome, myocardial

infarction, or stroke. Cataract is common in elderly patients and requires surgical cataract removal with intraocular lens implantation. Ocular surgeries, including cataract surgery (22.8%), were found to be 25% of total surgeries in the cohort and were 13% of the total estimated surgical need in

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the Indian population.¹ Antiplatelet therapy is discontinued before surgery to prevent ocular bleed (intra and post-operative). However, discontinuing these medications poses a risk for thromboembolic events, which can be life-threatening. Hence, it is important to balance the risks and benefits associated with and without stopping the antiplatelet therapy before cataract surgery. Earlier studies explained that antiplatelets need not be stopped before phacoemulsification cataract surgery.^{2,3} Interestingly, it was reported that out of the study patients who underwent cataract surgery, 28.1% were on aspirin, 5.1% on warfarin, and 1.9% on clopidogrel.⁴ Antiplatelet agents, when used either as monotherapy or dual therapy, have not been associated with an increased risk of hemorrhagic complications. However, if surgery is carried out under peri-or retro-bulbar anesthetic block, it is recommended that the P2Y₁₂ receptor inhibitors (clopidogrel) are discontinued perioperatively after the high-risk thromboembolic period.⁵ This is due to hemorrhagic risks associated with the anesthetic block rather than the cataract surgery itself. The National Institute for Health and Care Excellence guidelines recommend offering patients subtenon's, or topical (with or without intracameral anesthesia), for cataract surgery patients.^{6,7} Many studies reported that it is safe to continue antiplatelet drugs during surgery.⁸⁻¹¹ In India, the most commonly performed method of cataract surgery is manual small incision cataract surgery (MSICS). While various studies have established the safety of continuing anti-platelet drugs during phacoemulsification. Hence, the current study was undertaken to observe the effects of continuing antiplatelets when MSICS cataract surgery under subtenon's anesthesia is performed.

Aims and objectives

The current study was undertaken to observe the effects of continuing antiplatelets when MSICS cataract surgery under sub-tenon's anesthesia is performed.

MATERIALS AND METHODS

The present study was a prospective, comparative controlled trial. A total of 150 cases were recruited for the study. The study protocol was approved by the institutional human ethics committee (SPMCH/IEC/AP/03-2024-25) (August 12, 2024). The study was conducted from August 2024 to December 2024. Voluntary, written informed consent was obtained from all the participants of the study before the commencement of the study procedures. Patients posted for MSICS surgery were screened for exclusion criteria and were recruited for the study after obtaining written informed consent. The following is the criteria for inclusion/exclusion used in the study.

Inclusion criteria

1. The patients within the age group of 40–80 years
2. Have not undergone the ocular surgery
3. Willing to participate.

Exclusion criteria

1. Age <40 and >80
2. Complicated or traumatic cataract
3. Patients who have undergone previous ocular surgery
4. Patients not co-operative for subtenon's anesthesia.

After the recruitment, all the patients underwent a thorough preoperative eye examination, including vision, refraction, anterior segment, dilated fundus examination, and B scan when the fundus was not visualized. Patients were randomly assigned to two groups using random numbers generated by the software randomizer.org. Patients on antiplatelets as group 1, further divided as those on aspirin, clopidogrel, and dual antiplatelets for the purpose of analysis, and group 2 as patients not on antiplatelets (controls). Cataract nucleus grading was performed by considering the color of the nucleus on slit lamp biomicroscope and was graded as 1 for white to pale yellow, 2 for yellow, 3 for brownish yellow, and 4 for brown, black-brown.¹² Patients who were on antiplatelet drugs were asked to continue the medications. The operating surgeon was aware of the antiplatelets the patient was taking at the time of surgery. Fitness for surgery was obtained from the physician for all patients before surgery. The surgical procedure is as per the standard protocol. Perioperative intraocular minor complications such as subconjunctival hemorrhage (SCH) and its extent, hyphema, and any major complications such as vitreous, retrobulbar hemorrhage, were recorded. Patients were thoroughly examined by slit lamp on the 1st day, 1 week, 1-month post-surgery and looked for vision, anterior segment, and fundus with additional emphasis on intraocular bleed. Patients were also reviewed by a physician for thromboembolic events.

Surgical procedure

Under all aseptic precautions, two drops of 0.5% proparacaine hydrochloride eye drops and 5% povidine iodine drops were instilled 5 min before eye draping. Sub-tenon's anesthetic was injected by the surgeon after exposing the eye with a lid speculum. 2 mL of lignocaine hydrochloride 2% with adrenaline 1:200,000 was injected into the posterior sub tenon's space with a blunt subtenon's cannula under microscope after making a small conjunctival and tenon's capsule opening in the inferonasal quadrant, 5 mm away from the limbus. All patients were instructed to inform the doctor if they perceived pain during the injection or the procedure and were supplemented with intracameral preservative-free lignocaine when needed. All surgeries were performed by experienced surgeons

with minimal instrumentation. Steps like superior rectus bridle suture, cautery, and the use of toothed forceps were avoided. A self-sealing sclerocorneal tunnel was made in the superotemporal quadrant, followed by capsulorhexis. Nucleus was delivered out with the phacosandwich method after a thorough hydrodissection; cortex removal was done with a Simcoe's irrigation and aspiration cannula, and posterior chamber intraocular lens was placed in the capsular bag. 0.5 mL of subconjunctival dexamethasone and gentamicin was injected, and the eye was patched for 3 h.

Statistical analysis

Sample size (n) was calculated based on incidence of 40% SCH among patients on antiplatelets undergoing cataract surgery under subtenon's anesthesia compared to 19% SCH among patients not on antiplatelets therapy who are considered as controls (taken from a study titled Sub tenon's anesthesia with aspirin, warfarin, clopidogrel by Kumar et al.).¹² Using Open epi version 3.01, with the confidence level (1- α) of 95% with 80% power, the total cases that were studied are 150. A sample of about 75 in each group was estimated to see if the difference noted was-by chance or not.

Data were analyzed using the SPSS 24.0 version. The association between the groups was tested using the Chi-square test. The significance of the difference between the two groups was assessed using the Student's t-test. A probability value of <0.05 was considered statistically significant.

RESULTS

Seventy-five patients were on antiplatelets (group 1) and 75 were not on antiplatelets -controls (group 2). Of those on antiplatelets, 45 (60%) patients were on aspirin, 27 (36%) on clopidogrel, 3 (4%) on dual antiplatelet therapy. Table 1 presents the demographic data of the participants. Table 2 presents the systemic comorbidities of the patients. The numbers of patients having associations with systemic comorbidities such as diabetes mellitus, and hypertension were higher in group 1 (92%) compared to (34%) in group 2. Figure 1 presents the SCH in the participants on the first postoperative day. SCH incidence was higher in group 1 participants. SCH was resolved in both groups spontaneously without causing any visual disturbance at the end of 1-month post-surgical follow-up; both groups were similar (P=1.00). Table presents the comparison of vision on postoperative day one and postoperative day 30. Vision of better than 6/12 was noted in 68 (90.6%) patients in group 1 and 71 (94%) patients in group 2 on the first postoperative day (P=0.010) with no statistical

Table 1: Demographic data of the participants

Demographic details	Group 1 (Antiplatelets)	Group 2 (Control)
Number of patients (%)	75 (%)	75 (%)
Age (mean \pm SD)	63.6 \pm 8.49 years	59.7 \pm 10.1 years
Male	39 (52)	40 (53.3)
Female	36 (48)	35 (46.6)
Laterality		
Right eye	35 (46.6)	37 (49.3)
Left eye	40 (53.3)	38 (50.6)

Table 2: Systemic comorbidities in the participants

Co morbidity (DM/HTN)	Group	Counts	% of total
DM	Case group	6	4.0
	Control group	9	6.0
DM, HTN	Case group	36	24.0
	Control group	3	2.0
HTN	Case group	27	18.0
	Control group	14	9.3
NIL	Case group	6	4.0
	Control group	49	32.7

DM: Diabetes mellitus, HTN: Hypertension

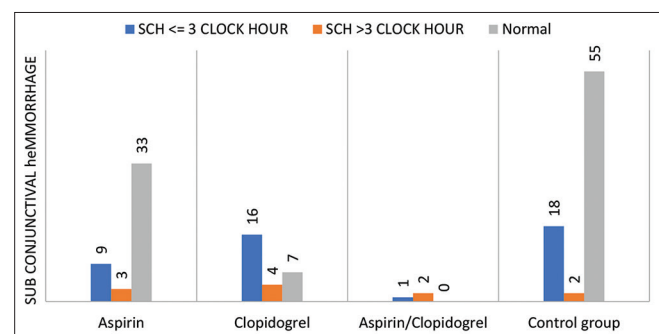


Figure 1: Subconjunctival hemorrhage in the participants on the 1st post-operative day

difference between the groups. At the end of the 1st month post-surgery 100% of patients in both groups had a vision better than 6/12 with no statistical difference between the two groups (P=0.422) (Table 3).

DISCUSSION

The present study results explain that it is safe to continue antiplatelets in MSICS performed under subtenon's anesthesia by an experienced surgeon. It was observed that many patients with cataracts are on antiplatelets for a systemic thromboembolic disorder like myocardial infarction, stroke, etc.¹² An earlier study explained that discontinuing aspirin for 7 days preoperatively and starting 3 days postoperatively caused a significant increase in major adverse cardiac events (9.0% vs. 1.8%, P=0.02) and was no significant difference to the perioperative blood loss in patients with stable cardiovascular disease

Table 3: Comparison of vision on postoperative day one and postoperative day 30

Independent samples T-test				
Parameter	Test applied	Statistic	df	P
Vision POD1 (2) ^a	Student's t	2.607	148	0.010
Vision POD30 (2) ^b	Student's t	-0.805	148	0.422

H₀: μ case group = μ control group^aLevene's test is significant (P<0.05), suggesting a violation of the assumption of equal variances^bAll observations are tied

undergoing high-risk elective surgery compared to those that continued aspirin perioperatively.¹³ Many studies explained that continuing the patients in the perioperative period in phacoemulsification cataract surgery is safe.^{9,10} Most clinicians in developing countries choose the MSICS as a major cataract surgery technique with potentially comparable results.¹³⁻¹⁶ The studies reporting the safety of the same in small incision cataract surgery performed under subtenon's anesthesia are sparse. The present study evaluated the incidence of various ocular hemorrhages, and no cases of retrobulbar or visually significant intra-ocular hemorrhage were found. One patient had a hyphema streak on the first postoperative day, which resolved in 2 days with treatment. In the current study, it was observed that 46% of patients on antiplatelets, which was statistically significant (P=0.047) compared to 26% in the control group. Konstantatos et al. reported the incidence of SCH with subtenon's injection to be up to 56% of cases.⁸ Another study conducted by Kobayashi et al., reported the incidence of sub-conjunctival hemorrhages to be 17.2% in patients on continued aspirin, warfarin, or both before subtenon's anesthesia, which was statistically significant compared to patients whose anti-thrombotic agents were discontinued for 1 week preoperatively.⁹ The present study results are in accordance with these studies.

Various methods have been suggested to decrease the incidence of SCH while performing subtenon's anesthesia, like using phenylephrine to constrict the vessels, conjunctival dissection under a microscope, and a new technique proposed by Chung et al., where conjunctiva is cauterized before making a nick with scissors.¹⁷ These methods could be sought in the future to give a cosmetically better picture post-surgery. Patients can also be informed about the occurrence of red eye post-surgery to decrease their apprehension. Continuation of aspirin and clopidogrel did not cause difficulty in stopping the bleeding in any individual case, and discontinuation of the medication did not affect the intraoperative course or postoperative outcome, similar to the study done by Assia et al., on aspirin continuation during cataract post-operative vision of all patients where all patients underwent normal surgery.^{18,19} Hence, it is safe to continue antiplatelets during MSICS

surgery under subtenon's anesthesia as all the patients had good vision postoperatively and no major complications were witnessed in the perioperative period.

Limitations of the study

The major limitation of this study is that we have not considered patients who are on anticoagulants. As the study was conducted in one area, the results of the study may not be generalized.

CONCLUSION

The present study results explain that it is safe to continue antiplatelets in MSICS performed under subtenon's anesthesia by an experienced surgeon.

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DP, AK, SS- Design of the study, review of literature, analysis and preparing the manuscript; SSKG, SS- Data collection, preparing the manuscript; SSKG, PD- Analysis and preparing the manuscript.

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