

# Safety Profile of Topical Phacoemulsification of Cataract in Patients Treated with Antiplatelet and Anticoagulant Drugs

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## ABSTRACT

**Introduction:** Patients undergoing cataract surgery are generally elderly, and on various medications for systemic diseases. The surgeon must have an idea of the risks of continuing or discontinuing these medications perioperatively. Antiplatelet drugs and anticoagulants, given to minimize the incidence of thromboembolic events, are often used in this age groups. The aim of present study was to evaluate the safety of phacoemulsification in cataract patients treated with anti platelet and anticoagulant drugs.

**Material and methods:** This present prospective case control study done on adult patients attending outpatient Department of Ophthalmology, Integral Institute of Medical Science and Research, Lucknow. The cases included patients of cataract on systemic antithrombotic therapy for various systemic disorders & were advised elective cataract surgery. Study included 50 cases on antithrombotic therapy and 50 controls which were age matched. Duration was from 1 February 2019 to 31 January 2020. After gaining approval from Institutional Research and Ethics Committee a written informed consent was obtained from each participant before including in the study.

**Results:** Study comprised of 63.0% males and 37.0% females patients and their mean age was  $62.5 \pm 13.6$  years. Among cases 40% patients were on Aspirin, 30% on warfarin and 30% on a combination therapy of aspirin and clopidogrel and indications were Stroke Prophylaxis (16%), Valve replacement (6%), Coronary artery bypass (18%), Coronary artery stents (4%), Post stroke (26%) and Atrial Fibrillation (30%). There was no statistically significant difference between the cases and the controls in the per operative, post operative day 1 and post operative one week follow up of bleeding assessment ( $P < .005$ ).

**Conclusions:** Clear corneal phacoemulsification performed under topical anesthesia, was not associated with significant perioperative bleeding risk & can be safely performed in simple cases of cataract with continuing treatment.

**Keywords:** Phacoemulsification; Bleeding; Anticoagulants

## INTRODUCTION

According to the World Health Organization, cataract surgery is the most commonly performed ocular surgical procedure in the world.<sup>1,2</sup> The population of people over 65 years of age is likely to double in the next decade, many of whom would be requiring cataract surgery. A large proportion of these individuals also have age-related comorbidities, for which they take different drugs with a variety of systemic side effects.<sup>3</sup> The cataract surgeon must assume the risk of perioperative complications posed by a few of these agents<sup>4</sup>,

that are typically prescribed for this age group.<sup>5</sup> Antiplatelet agents (Ap) and anticoagulants (Ac) are used to reduce the risk of thromboembolic events in coronary heart disease patients with intracoronary stents requiring the use of two Ap drugs for a short period of time or other cardiovascular diseases, such as atrial fibrillation.<sup>6,7</sup> The discontinuation of antithrombotic treatment in order to reduce the risk of bleeding during cataract surgery might be considered routine by some, but it may be potentially injurious for patients who are at an increased risk of thrombosis.<sup>8</sup> Thus there is difference of opinion about whether to stop anticoagulants or antiplatelet agents before cataract surgery.<sup>9</sup> Patients taking such agents may be at greater risk for ocular hemorrhages, but if such therapy is stopped before surgery, patients may increase their risk of medical events for which the therapy was indicated. Some studies have observed the issue of whether to stop anticoagulant or antiplatelet therapy before ocular surgery, and most of the studies had inadequate sample size or lacked a control group.<sup>10-12</sup> The use of anticoagulant or antiplatelet therapy is common, especially amongst elderly patients, as it has been shown to minimize the risk of thromboembolic complications in patients with many coronary and vascular conditions.<sup>13-15</sup> Hence, there is an issue of whether the risk of unfavorable medical events on temporarily stopping anticoagulant or antiplatelet therapy before cataract surgery outweighs the benefits of less hemorrhagic events if continued. In this study, we analyzed prospectively the outcome of phacoemulsification in cataract patients treated with antiplatelet and anticoagulant drugs and monitored by laboratory analysis.

## MATERIAL AND METHODS

This study was a prospective, case control study conducted at Department of Ophthalmology, Integral Institute of Medical Science and Research, Integral University, Lucknow, Uttar

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**How to cite this article:** Mobin M, Kanodia P, Malhotra R. Safety profile of topical phacoemulsification of cataract in patients treated with antiplatelet and anticoagulant drugs. International Journal of Contemporary Medical Research 2020;7(11):K7-K12.

**DOI:** <http://dx.doi.org/10.21276/ijcmr.2020.7.11.20>



Pradesh, India after gaining approval from Institutional Research and Ethics Committee. The study duration was from 1 February 2019 to 31 January 2020. The study subjects were chosen from adult patients who presented to the outpatient Department of Ophthalmology, Integral Institute of Medical Science and Research, Lucknow for elective cataract surgery and who were on systemic antithrombotic therapy. Written informed consent was obtained from each participant, which included an explanation of the study design and goals. Details of antithrombotic therapy viz. drug, dose, indication, duration, thrombo-embolic event, hemorrhagic complications if any were recorded in detail during the recruitment. Controls were selected from cataract patients fit to undergo topical phacoemulsification without any exposure to antithrombotic therapy with matching in terms of age, grade of cataract etc. This study included 50 cases on antithrombotic therapy undergoing elective topical phacoemulsification cataract surgery and 50 controls.

#### Sample size

A total of 100 patients with senile cataract were enrolled in the study. The subjects were divided into 2 groups, the cases and the controls. The case group included 50 patients on Anti-thrombotic therapy fit for topical phacoemulsification cataract surgery. Control group included 50 cases without any exposure to Anti-thrombotic therapy but with a similar profile in terms of age, grade of cataract undergoing topical phacoemulsification cataract surgery.

#### Method

Per-operative bleeding was assessed in terms of site and how it was managed and was graded by the surgeon. Post-operative bleeding in terms of subconjunctival hemorrhage, hyphaema, vitreous bleed, retinal bleed and suprachoroidal hemorrhage if any were recorded. The bleeding complications if any were recorded intraoperatively, on the first post-operative day and at one week follow up. Bleeding was recorded as significant if interfered with the surgeon's view of the operating field and was difficult to stop. Post-operative significant complications were recorded as significant if bleeding affected the visual acuity of the patient and/or did not resolve at 1 week follow up.

#### Inclusion criteria

- Age > 40 years
- Able to understand and give consent
- All patients on antithrombotic therapy (Case) & not on antithrombotic therapy (Control)
- Fit for topical Phacoemulsification
- Able to follow the scheduled visit protocol

#### Exclusion criteria

- Previous surgery in the same eye
- Patients scheduled for cataract surgery combined with trabeculectomy or pars plana vitrectomy
- Patients with phacodonesis
- Patients with pupil dilation less than 4mm
- Patients with presence of pathological vessel in the eye (eg. Iris, angle or corneal neovascularization)
- Patients with angle closure glaucoma

- Patients who were allergic to proparacaine hydrochloride
- Any complication occurring per operatively that would require conversion of procedure/ supplementation of anesthesia

#### Preoperative work-up

All patients were subjected to comprehensive ophthalmic assessment which was as follows: non-contact tonometry, visual acuity, refractive status, dilated slit lamp examination and fundus examination, syringing, biometry & systemic assessment including B.P. measurement & ECG recording. Laboratory investigations included: conjunctival culture and sensitivity, random blood sugar, complete blood count was recorded in each patient one day before surgery. For patients who were on antiplatelet therapy: bleeding time and clotting time was recorded one day before surgery. For patients who were on anticoagulant: PT, INR, aPTT were recorded one day before surgery & those with normal values were included in the study.

#### Preoperative Advice

Patients were advised to continue the systemic medication by the consulting physician. Topical antibiotic eye drop were started 1 day prior in the planned eye 4 times/day till the day of the procedure.

#### Surgical procedure

Topical Proparacaine hydrochloride 0.5% was instilled immediately after entering the operating room prior to cleaning and draping and after insertion of eye speculum. Surgical procedure began with a clear corneal side port at 1 o'clock through which air, dye and viscoelastic were injected. Clear corneal 2.8mm incision was given at 10 o'clock and capsulorhexis was done using cystitome. Hydro dissection was done followed by chopping of endonucleus by phacoemulsification probe and extracted using stop and chop technique followed by bimanual irrigation and aspiration to wash out the cortical matter. Foldable intraocular lens was implanted in the bag. Residual viscoelastic was aspirated and anterior chamber was formed with air and saline. Intracameral preservative free moxifloxacin was injected and section was - closed with stromal hydration.

Peroperative assessment of bleeding / hemorrhagic complication was done by the surgeon with reference to site of bleeding and how it was managed and if the bleeding was significant enough to obscure the operative field of the surgeon. All this was recorded and graded as per proforma.

#### Follow-up evaluation and outcome measures

Follow-up visits were scheduled on first and seventh postoperative day. Post-operative bleeding in terms of sub conjunctival haemorrhage, hyphaema, vitreous bleed, retinal bleed and suprachoroidal hemorrhage if any were recorded at postoperative day 1 and at one week follow up. Post-operative best corrected visual acuity was also recorded.

#### STATISTICAL ANALYSIS

The analysis of data was generally descriptive, involving determination of frequencies. Microsoft excel was used to analyze the data with SPSS 16 package .

**RESULTS**

There was a total of 100 patients; 63 males (63.0%) and 37 females (37.0%) with mean age  $62.5 \pm 13.6$  years. Patients were divided into two equal groups, Cases: Cataract patients who were on antithrombotic therapy and control: Cataract patients who were not on antithrombotic therapy. Mean ages in cases and controls were  $63.2 \pm 12.6$  and  $62.8 \pm 12.9$  respectively.

Table 1 shows that, among cases 20 patients were on Aspirin, 15 on warfarin and 15 on a combination therapy of aspirin and clopidogrel. There are 26 male patients and 24 female patients. Eight (40.0%) males and 12 (60.0%) females were on Aspirin, 10 (66.67%) males and 5 (33.33%) females were on warfarin, 8 (53.33%) male and 7 (46.67%) females were on combination therapy of aspirin and clopidogrel. The average duration of drug therapy were 8 years, 5 years and 5.5 years respectively for Aspirin, Warfarin and combination of both Aspirin and Clopidogrel. Among control there were

38 (76.0%) males and 12 (24.0%) females.

Figure 1 depicts that the grade of cataract with respect to cases and control, In which most of the cases and controls belongs to the grade 2 (Nuclear Sclerosis grade 3 with Cortical cataract 0/1/2 with Posterior subcapsular cataract 0/1/2). Whereas, 10 controls who were not on antithrombotic therapy belongs to Nuclear Sclerosis grade 4 with Cortical cataract 0/1/2/3 with Posterior subcapsular cataract. Figure 2 is depicting the various indications for using Antithrombotic therapy in the case group.

Table 1 shows the sex distribution in two groups. Table 2 shows that the pre-operative blood investigations in patients on anticoagulant therapy included PT, aPTT, INR which had a median of 12 seconds, 30 seconds and 1.06 respectively, For the patients on antiplatelet therapy the blood investigations done were bleeding time, clotting time and platelet count which had a median of 144 seconds, 200 seconds and 173000/ cubic millimeter respectively, which were within

Groups	Drug therapy	Gender		Total
		Male	Female	
Controls		38(76.0%)	12(24.0%)	50
Cases	Aspirin	8(40.0%)	12(60.0%)	20
	Warfarin	10(66.67%)	5(33.33%)	15
	Aspirin and Clopidogrel	8(53.33%)	7(46.67%)	15
Total		64(64.0%)	36(36.0%)	100

**Table-1:** Distribution of drug therapy w.r.t to gender in study population.

Investigations	Median	Standard Deviation
Anticoagulant therapy		
Prothrombin Time (seconds) (PT)	12	0.62
Active partial thromboplastin time (Seconds) (aPPT)	30	1.80
International Normalized Ratio	1.06	0.13
Antiplatelet therapy		
Bleeding Time (Seconds) (BT)	144	17.31
Clotting Time (Seconds) (CT)	200	13.01
Platelet Count (Per Cubic Millimeter)	1,73,000	34457.91

**Table-2:** Baseline clotting profile in patients on anticoagulant and antiplatelet therapy

	Peroperative and Postoperative Events	Results
Per operative events	Subconjunctival Bleed	Nil
	Hyphaema	1 (Mild in Case)
	Effect on surgical Viewing Field	Nil
Post operative day 1 events	Subconjunctival Bleed	2 (1 in case & 1 in control)
	Hyphaema	Nil
	Vitreous Bleed	Nil
	Retinal Bleed	Nil
	SuprachoroidalHaemorrhage	Nil
	Visual outcome (Excellent > 6/18)	Nil
Post operative follow up at 1 week events	Subconjunctival Bleed	Nil
	Hyphaema	Nil
	Vitreous Bleed	Nil
	Retinal Bleed	Nil
	SuprachoroidalHaemorrhage	Nil
	Visual outcome (Excellent > 6/18)	Nil

**Table-3:** Showing the results at peroperative, post operative day 1 and post operative follow up at 1 week in cases and controls.

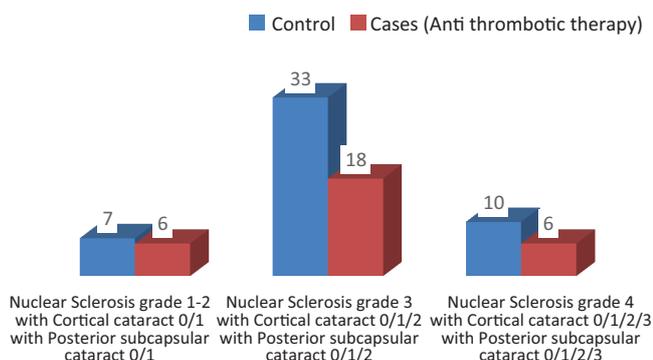


Figure-1: Distribution of cataract grade between cases and control

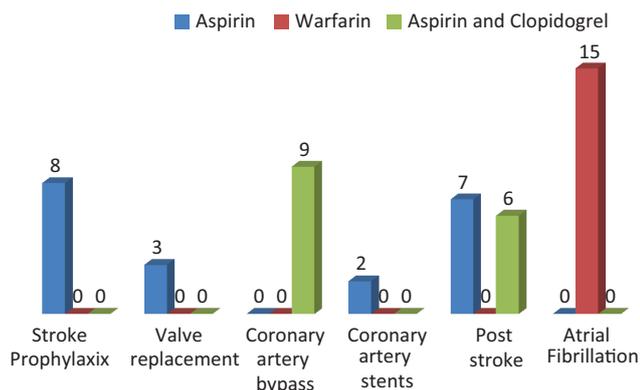


Figure-2: Indication of therapy for cases on antithrombotic therapy

normal reference ranges.

Table 3 shows that the, per operative bleeding was assessed in terms of subconjunctival bleed, iris bleed/hyphaema and any hindrance in the surgeon's operating field. Post operative events were assessed at day one and at one week follow up. At post operative day 1 the bleeding was measured in terms of subconjunctival bleed, iris bleed / hyphaema, vitreous bleed, retinal bleed and suprachoroidal haemorrhage. One case & one control had mild subconjunctival bleed on first postoperative day. Both the groups had an excellent visual outcome (visual acuity >6/18). At post operative one week follow up the bleeding was measured in terms of subconjunctival bleed, iris bleed/hyphaema, vitreous bleed, retinal bleed and suprachoroidal haemorrhage. There was no statistically significant difference between the cases and the controls in the per operative, post operative day 1 and post operative one week follow up bleeding assessment. There was no difference in the visual outcomes between the two groups at post operative one day and one week follow up. Both the groups had an excellent visual outcome (visual acuity >6/18).

**DISCUSSION**

Most of patients undergoing cataract surgery are elderly and on regular systemic medications. Significant classes of drugs to identify include antiplatelet and anticoagulant medications, which may raise the risk of hemorrhagic complications, intraoperatively & postoperatively. These medications are, taken to reduce the incidence of potentially life-threatening thromboembolic events in patients with cardiovascular conditions.<sup>13-20</sup> A large proportion of these

persons also have age-related comorbidities, for which they take drugs with various systemic effects.<sup>3</sup> The present study included, males 63.0% and females 37.0% with mean age 62.5 ± 13.6 years. Among cases 40% patients were on Aspirin, 30% on warfarin and 30% on a combination therapy of aspirin and clopidogrel indication of patients were Stroke Prophylaxis (16%), Valve replacement (6%), Coronary artery bypass (18%), Coronary artery stents (4%), Post stroke (26%) and Atrial Fibrillation (30%). Moreover, the important indications for these drugs are in managing or prevention of thromboembolic events in disorders such as stroke, acute myocardial infarction, angina, cardiac surgery, prosthetic heart valves, acute coronary syndrome, pulmonary embolism, venous thromboembolism, and atrial fibrillation.<sup>21-23</sup> According to current guidelines, some form of antithrombotic treatment is indicated in 70% to 80% of patients with atrial fibrillation and in 20% to 30% of patients with coronary artery disease.<sup>24</sup> This study on continuation of antithrombotic therapy during clear corneal topical phacoemulsification cataract surgery showed no bearing of such therapy on the risk of bleeding complications and the visual outcome during the perioperative period between the cases and the controls. The observations of this study are consistent with those reported by Assia El et al<sup>25</sup>, Grzybowski et al<sup>3</sup> and Cheung et al.<sup>26</sup> Assia et al concluded that the post-surgical appearance of the patients was similar in all groups. and there, were no more subconjunctival hemorrhages in patients under therapy than in those ,who discontinued aspirin.<sup>25</sup> Also cheung et al., observed no significant difference in intra-operative, post operative and systemic complications between patients who continued therapy and concluded that anticoagulant therapy is safe to be continued in patients undergoing phacoemulsification cataract surgery and there were no intra operative and post operative bleeding complications in both their cases and control group.<sup>26</sup> The following non ophthalmic surgical study on patients undergoing surgical procedures with continuation of anticoagulant and antiplatelet therapy had observations similar to this study: Lindblad et al concluded that most of the listed studies on aspirin induced bleeding complications had little statistical power. When surgeons were blinded regarding aspirin application, they could not differentiate patients on aspirin from patients off aspirin just from bleeding profile.<sup>27</sup> However, Wirbelauer et al., in their prospective case control study had observation which was in contrast to the present study.<sup>28</sup> These bleeding complications were non sight threatening and resolved spontaneously within few days .Most of the previously reported studies for evaluating the safety continuation of oral anticoagulant and antiplatelet therapy during clear corneal phacoemulsification cataract surgery under topical anesthesia suffer common deficiencies such as, small number of cases, absence of controls/disproportionate controls, non randomization and non-inclusion of difficult cases such as those with ocular co morbidities, poorly dilating pupil, phacodonesis or subluxation of lens. The present study concluded that the patients undergoing clear corneal phacoemulsification

cataract surgery under topical anesthesia, who were on anticoagulant and antiplatelet therapy had no significant difference in bleeding complications and visual outcome during the intra-operative and post operative period in comparison to controls (Not on anticoagulant and antiplatelet therapy).

## CONCLUSION

All patients had an excellent visual recovery. Study concluded that continuation of antithrombotic therapy is a safe practice concerning the perioperative bleeding risk in patients, schedule for clear corneal phacoemulsification under topical anesthesia.

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**Source of Support:** Nil; **Conflict of Interest:** None

**Submitted:** 20-10-2020; **Accepted:** 15-11-2020; **Published:** 30-11-2020