Revista Argentina de Clínica Psicológica
2020, Vol. XXIX, N°4, 371-376
DOI: 10.24205/03276716.2020.836

Complicated Phacoemulsification Cataract Surgery in Patients Treated with Aspirin

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Abstract

Purpose: To evaluate the incidence of intraoperative and postoperative complications associated with the continuation of aspirin use before complicated phacoemulsification cataract surgery (CPCS).

Materials and Method: This prospective study included 85 consecutive patients who had CPCS with a clear corneal incision under topical anesthesia between October 2016 and April 2018. One hundred and eleven eyes from 85 patients using aspirin over long-term were randomized into two groups: maintenance group (55 eyes) that included patients who continued using aspirin until the day of surgery; discontinuation group (56 eyes) that included those who stopped using aspirin 3 to 7 days before surgery. Besides, 56 eyes (44 patients) with no antiplatelet/anticoagulant therapy were used as a control group. Preoperative, intraoperative and postoperative complications were recorded.

Results: No patients suffered from thromboembolic events during the follow-up period. There was no significant difference in the incidence of hemorrhagic complications and nonhemorrhagic complications among the three groups (p=0.594 and p=0.714, respectively). The incidence of subconjunctival hemorrhage in the control group was higher than that in the maintenance group and discontinuation group, but there was no significant difference (p= 0.711). In the maintenance group and the control group, postoperative hyphema (< 1.0mm and = 2.0mm, respectively) was observed in one case of each group (one eye) and was spontaneously relieved. In addition, no cases of choroidal/suprachoroidal hemorrhage, vitreous hemorrhage, retinal detachment, or endophthalmitis were observed.

Conclusions: Our outcomes indicate that CPCS with a clear corneal incision under topical anesthesia could be safely performed without discontinuing systemic aspirin therapy.

Keywords: complicated phacoemulsification cataract surgery; aspirin; cataract surgery complications

Introduction

A cataract is a medical condition, also known as a clouding of the normally clear lens of the eye. According to the WHO (World Health Organization), approximately 95 million of people are affected by cataracts. Surgery is considered the only effective treatment for a patient with cataract[1]. Before and after surgery, medication is commonly applied to reduce scarring, modulate healing, and improve recovery.

Previous studies have reported that 20% of patients take aspirin routinely before Operation Cataract, 2.3. Aspirin was the foundation for the prevention and treatment of life-threatening vascular problems, especially in elderly patients. with coronary artery, cerebrovascular, and peripheral vascular diseases[4-8]. Aspirin mediates the cardioprotective effect by inhibiting platelet cyclo-oxygenase 1 and suppression of thromboxane A2. Besides, aspirin has shown promising benefits for those at risk of cancer, such as adenomas and colorectal cancer[9,10].

In recent years, there has been a discussion on the need to avoid anticoagulant or Antiplatelet therapy before cataract operation, which has a reduced rate of complications. It is impossible to determine if a short end of therapy will extend the length of therapy. likelihood of complications during surgery, e.g. causing perioperative hemorrhagic complications, rendering surgery clinically difficult

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due to reduced surgical vision and ultimately contributing to failure of surgery. There is currently no Guideline for the perioperative management of aspirin in patients taking long-term antiplatelet therapy planned to conduct cataract surgery.The purpose of this study was to evaluate the incidence of intraoperative and postoperative problems correlated with the continuous use of aspirin prior to cataract surgery.

Materials and Methods

Patients

The prospective randomized research included 85 patients who underwent CPCS with a clear corneal incision at Huashan Hospital, Fudan University, Shanghai, China between October 2016 and April 2018. All patients were using aspirin. One hundred and eleven eyes from 85 patients were randomized into 2 groups: maintenance group (55 eyes) that included patients who continued using aspirin until the day of surgery; discontinuation group (56 eyes) that included those who stopped using aspirin 3 to 7 days before surgery. Besides, 56 eyes (44 patients) with no antiplatelet/anticoagulant Treatment has been viewed as a monitoring group. Patients were randomised to a table of random numbers.The research procedures have been approved by the Institutional Review Board of Huashan Hospital associated with Fudan University and have been carried out in compliance with the Helsinki Declaration. The formal informed consent of each patient was obtained.

Inclusion and exclusion criteria

Inclusion criteria were nuclear hardness over grade IV, high myopia up to –12.0 diopters (D), previous operation (e.g., trabeculectomy, or pars plana vitrectomy) in the same eye, pupil dilatation < 4.0 mm, uncontrolled glaucoma, existence of pathological vessels in operative eye (e.g., iris neovascularization or proliferative diabetic retinopathy), and severe renal failure. Exclusion criteria were fasting glucose > 9mmol/L, blood pressure>170/90mmHg, and those using other kinds of antiplatelets and/or anticoagulants.

Data Collection

All patients underwent preoperative and postoperative (day 1 and day 7 after surgery) Assessment, like slit-lamp biomicroscopy, best-corrected visual acuity (BCVA), intraocular pressure (IOP), and funduscopic review. The BCVA has been transformed to the logMAR type used in all statistical analyses. Hypotony and IOP elevations were described as IOPs < 9 mmHg and > 30 mmHg respectively. Both intraoperative and postoperative problems were registered.

Surgical Technique

Normal transparent corneal phacoemulsification with post-chamber intraocular lens implantation under topical anaesthesia was conducted by four professional surgeons in the same institution. Patients got topical anaesthesia with tropicamide eye drops including tropicamide (0.5 per cent), phenylephrine hydrochloride (0.5 per cent) and Oxybuprocaine Hydrochloride (20 ml: 80 mg). Surgeries were randomized, and all surgeons were blind to the grouping.

Statistical Analysis

Both analyses were based on the intention-to-treat concept and were carried out using SPSS for Windows Version 24.0 (SPSS, Inc., Chicago, IL, USA). A two-size P value of < 0,05 was found statistically important. Continuous variables are represented as mean ± standard deviation (SD). Classic variables were expressed as frequencies and percentages. The ANOVA was used for continuous data purposes. The chi-square test was used to evaluate categorical variables between maintenance group, discontinuation group, and control group. As small numbers showed that the chi-square test could be invalid, the same Fisher test was used.

Result

A total of 111 eyes from 85 patients were examined. The mean duration for aspirin the period of therapy until surgery was 70.8 months (range, 11€-240 months). Characteristics of patients seen in table 1. Statistical analysis has found that the proportion of male and female patients is exactly the same. In comparison, there were no variations in demographics, initial BCVA, initial IOP, physicians, period of aspirin consumption and systemic evidence of class-specific antiplatelet therapy(Putrawan et al., Rabathaly & Chattu, 2019; Rani & Kumari, 2019; Park et al., 2019).

The most common complications observed before surgery are shown in Table 2. In all three groups, nuclear hardness over grade IV was the most common complication, followed by high myopia up to –12.0 D, previous operation in the same eye, severe renal failure, uncontrolled glaucoma, pupil dilatation <4.0 mm, and existence of Pathological vessels of the organisational eye.

Cardiovascular diseases, cerebrovascular diseases, and carotid plaque were the Most prominent medical problems in the Rehabilitation and Discontinuation Culture of atrial fibrillation, coronary artery bypass graft, and cardiac pacemaker. In comparison, there was no substantial variation in the number of people with the same medical conditions (Table 3). Changes in postoperative BCVA and IOP are shown in Table 4. The surgical Intervention increased visual acuity in three categories. BCVA was increased one week after surgery from 1.50 ± 0.88 to 0.35 ± 0.22 in the maintenance community ($p<0.05$), 1.41 ± 0.92 to 0.39 ± 0.23 in the discontinuation category ($p<0.05$), and 1.41 ± 0.69 to 0.34 ± 0.32 in the monitoring group ($p<0.05$), respectively. There was no substantial gap between the three classes in one postoperative day and one-week postoperative BCVA (p=0.767).and p=0.553, respectively). There were also no significant differences in final intraocular pressures among all groups (p=0.480). Table 5 shows the incidence of hemorrhagic and nonhemorrhagic adverse events after the operation. No patients suffered from systemic complications during the follow-up period. There was no significant difference in the incidence of hemorrhagic Complications in three classes (p=0.594). Of the hemorragic complications, subconjunctival hemorrhoea was the most common complication; while the occurrence of subconjunctival hemorrhoea in the control community was higher than the maintenance and discontinuation category, there was no statistical difference (p=0.711). In comparison, no patient needed further hospital visits for subconjunctival haemorrhage.

A 45-year-old male with an iris was in the repair category. neovascularization who suffered from postoperative hyphema (< 1.0mm), which spontaneously resolved without permanent sequelae. In the control group, there was an 80-year-old female with a previous trabeculectomy and the postoperative hyphema occurring in the same eye (=2.0mm) that faded away spontaneously without affecting visual acuity. Furthermore, we found no statistical difference in nonhemorrhagic adverse events, such as hypotony, elevated IOP, corneal edema and posterior capsule rupture. Corneal Edema was the most common non-hemorrhagic complication, which spontaneously faded away without therapeutic implications within a week. Both IOP improvements returned to usual levels after one week. In the discontinuation community, an 82 year-old patient with an intraoperative rupture of the posterior capsule had intraoperative implantation of IOL with no clinical implications.

Discussion

This prospective, randomized study demonstrated that CPCS could be safely performed in patients with aspirin therapy. There was no increase in adverse events in patients who continued using aspirin compared to those who stopped aspirin therapy few days (4 to 7 days) before surgery or those who were not on aspirin therapy (control group). No intraoperative hemorrhage was observed. Although subconjunctival hemorrhage was the most frequent hemorrhagic complication, it was self-limiting in three groups. Corneal edema was the most common nonhemorrhagic complication that was spontaneously relived within a week without causing clinical consequences.

In a case series of 355 patients (558 eyes) receiving antiplatelet or anticoagulant therapy, Kobayashi *et al* [11] discovered a significant increase in the incidence of subconjunctival hemorrhage compared with those who discontinued therapy for 1 week before surgery (16.5% versus 10.8%; p=0.0309). Nevertheless, there were no detailed stratified records on patients who took aspirin alone, despite that they accounted for more than 70% of all the included subjects. Besides, in this study, patients were treated with sub-Tenon anesthesia of lidocaine, which could cause hemorrhage; subconjunctival hemorrhage is the most frequent minor complication in patients receiving sub-Tenon anesthesia.

Our study results were consistent with some other studies; however, these were somewhat restricted in the context of uncomplicated cataract surgery. For example, Benzimra *et al*[3] analyzed 55,567 surgeries from the U.K. Cataract National Dataset and discovered no increase in hemorrhagic or anesthetic complications in patients taking aspirin alone. Moreover, Grzybowski *et al*[12] reviewed the PubMed articles on possible complications in patients undergoing cataract surgery and receiving anticoagulant and/or antiplatelet therapy published between 2007–2013, reporting that antithrombotic therapy was recommended for routine, uncomplicated cataract surgery. However, under some complicated conditions such as small pupils, which may increase the risk of hemorrhage, the decision to suspend antiplatelet or anticoagulant therapy

should be carefully considered.

Following the development of surgical equipment and techniques, increasing number of studies have suggested that antiplatelet medications in cataract surgery lead to no sight-threatening complications and are generally safe [2,13,14]. Moreover, the Cataract in the Adult Eye Preferred Practice Pattern of the American Academy of Ophthalmology recently suggested that aspirin can only be stopped if the possibility of bleeding reaches its possible benefit15.

However, with cataract surgery proven to be secure and successful and the indications for cataract surgery extended, more and more patients with differing complexity are undergoing cataract surgery.

Kong *et al* analyzed the literature available at MEDLINE and EMBASE electronic databases published from 1994 to 2014, and concluded that routine cataract surgery is safe for patients using antiplatelet agents[16]. For complex surgeries, there should be a multidisciplinary discussion. In addition, due to changing patient demographics, it was suggested to continuously review the evidence to instruct clinical practice.

As the supplement of the studies mentioned above, our data suggested that aspirin does not affect and cause complications in patient undergoing complicated cataract surgery. However, there are some points that should be considered before surgery. According to our previous study, a clear corneal incision is better than scleral tunnel incision in patients treated with aspirin. In the current study, topical anesthesia resulted more beneficial than sub-Tenon anesthesia.

The present study has some limitations. Firstly, sample size was too small. Secondly, it was difficult to precisely quantify perioperative bleeding. However, every effort was made to afford a clinically meaningful classification of hemorrhagic complications. Thirdly, the patients who need long-term antiplatelet therapy were likely to have more general vascular damage, which put routine aspirin users at higher risk for hemorrhagic complications. A comparison of routine users who maintain or continued medication likely reduced the bias. Finally, the cohort was designed to include mixed population. It is not possible to draw conclusions in regard to the specific risk of each inclusion condition. However, the results are meaningful in assessing the general risk of inclusion conditions.

Conclusions

Our outcomes indicate that CPCS under topical anesthesia with clear corneal incision can be safely performed without ceasing systemic aspirin therapy.

Conflict of interest

None declared

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Table 1. **The patients' characteristics**

Parameter	Maintenance group	Discontinuation group	Control group	P value [a]
Patients, n	42	43	44	—
Eye, n	55	56	56	—
Male, n	25	21	21	0.485
Age(year), mean (SD)	74.51(10.39)	74.11(8.12)	72.39(7.39)	0.398[b]
Range	45 – 88	45 – 88	54 – 85	
BCVA (logMAR), (SD)	1.50(0.88)	1.41(0.92)	1.41(0.69)	0.793[b]
IOP (mmHg), mean (SD)	15.65(2.74)	15.70(2.93)	15.46(3.09)	0.905[b]

SD=standard deviation; BCVA = best corrected visual acuity; IOP = intraocular pressure;
[a]Chi-square test; [b] ANOVA=analysis of variance

Table 2. **Complication before surgery in different groups**

Indication	Eyes, n (%)

	Maintenance group n=55	Discontinuation group n=56	Control group n=56	P Value [a]
Nuclear hardness over grade IV	31 (56.4%)	27 (48.2%)	28 (50.0%)	0.666
High myopia up to –12.0 D	12 (21.9%)	14 (25.0%)	17 (30.3%)	0.582
Previous operation in the same eye	2 (3.6%)	4 (7.1%)	4 (7.1%)	0.668[c]
Severe renal failure	4 (7.3%)	3 (5.4%)	3 (5.4%)	0.600[c]
Uncontrolled glaucoma	2 (3.6%)	4 (7.1%)	2 (3.6%)	0.600[c]
Pupil dilating to be short of 4.0 mm	2 (3.6%)	3 (5.4%)	1 (1.8%)	0.597[c]
Existence of pathological vessels	2 (3.6%)	1 (1.8%)	1 (1.8%)	0.763[c]

[a] Chi-square test; [c] Fisher exact test

Table 3. **Systemic indication for antiplatelet therapy**

Systemic indication for antiplatelet therapy	Eyes, n (%) Maintenance group n=55	Discontinuation group n=56	P value [a]
Ischemic cardiovascular diseases	27 (49.1%)	26 (46.4%)	0.779
Ischemic cerebrovascular diseases	12 (21.8%)	15 (26.8%)	0.542
Carotid plaque	1 (1.8%)	2 (3.6%)	1.000[c]
Atrial fibrillation	3 (5.5%)	2 (3.6%)	0.679[c]
Coronary artery bypass graft	1 (1.8%)	1 (1.8%)	1.000[c]
Cardiac pacemaker	2 (3.6%)	0 (0)	0.243[c]
Patients without certain indication	9(16.4%)	10(17.8%)	0.835

[a]Chi-square test; [c]Fisher exact test.

Table 4. **Postoperative BCVA and IOP**

Parameter	Maintenance group n=55	Discontinuation group n=56	Control group n=56	P Value [c]
One day postoperative				
BCVA, logMAR	0.64 ± 0.74	0.70 ± 0.68	0.61 ± 0.62	0.767
IOP, mmHg	17.40 ± 3.73	17.93 ± 5.68	17.93 ± 6.38	0.811[b]
One week postoperative				
BCVA, logMAR	0.35 ± 0.22	0.39 ± 0.23	0.34 ± 0.32	0.553
IOP, mmHg	15.95 ± 2.75	16.07 ± 2.89	15.43 ± 3.19	0.480[b]

[b] ANOVA=analysis of variance; [c] Fisher exact test.

Table 5. **Number and types of adverse events among three groups**

Complication	Eyes, n (%) Maintenance group n=55	Discontinuation group n=56	Control group n=56	P value [a]
Hemorrhagic complication				
Subconjunctival hemorrhagic	6 (10.9%)	4 (7.1%)	4 (7.1%)	0.711[c]
Hyphema	1 (1.8%)	0 (0)	1 (1.7%)	0.600[c]
Nonhemorrhagic complication				
Corneal edema	12 (21.8%)	11 (19.6%)	12 (21.4%)	0.956
Hypotony (<6 mmHg)	1 (1.8%)	3 (5.4%)	2 (3.6%)	0.605[c]
IOP elevation (>30 mmHg)	0 (0)	1 (3.0%)	3 (5.4%)	0.170[c]
Posterior capsule rupture	0 (0)	1 (3.0%)	0 (0)	0.369[c]

[a] Chi-square tests.
[c] Fisher exact test.