Thai J Ophthalmol 2564;35(1):1-10.

Original Article

A Comparative Study of Ocular Hemorrhage in Cataract Surgery Patients Receiving Continuous Antithrombotic and with Preoperative Discontinuation

การศึกษาเปรียบเทียบภาวะเลือดออกในตาของผู้ป่วยผ่าตัดต้อกระจกที่ได้รับยาต้านเกล็ดเลือดหรือยาต้านการแข็งตัวของเลือดต่อเนื่อง และแบบหยุดยาก่อนการผ่าตัด

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Abstract

Objective: To compare the incidence of ocular hemorrhage in cataract surgery between patients who continue antithrombotic and with preoperative discontinuation.

Method: A retrospective cohort study of patients who on antiplatelet or anticoagulant drugs undergoing cataract surgery between January 2020 and December 2020 were eligible in the study. Patients discontinued antithrombotic drugs 5-7 days before surgery (discontinuation group) or continued therapy until the time of surgery (maintenance group). Patients were examined 1 day, 7 days and 1 month postoperatively. Intraoperative and postoperative ocular bleeding and systemic complications were assessed.

Main outcome measures: Intraoperative and postoperative ocular hemorrhage and thromboembolic complications.

Results: 288 eyes of 274 patients were included in the study. The maintenance antiplatelet/anticoagulant group comprised 115 eyes, the discontinuation group comprised 173 eyes. There was no sight threatening intraoperative bleeding. Sixty-eight eyes (40.5%) in the discontinuation antiplatelet group and twenty-six eyes (24.5%) in the maintenance antiplatelet group had subconjunctival hemorrhages (p=0.01), associated with local anesthesia (OR 48.78, 95%CI 18.45-

Conflicts of interest: None

Approved from the IRB of Trang Hospital: Research ID003/Study code:02-2564.

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128.97). Using multivariable analysis, maintenance antiplatelet did not increase risk of subconjunctival hemorrhage (OR 0.55, 95%CI 0.27-1.11). There was no significant difference regarding hemorrhages between the discontinuation and the maintenance group in anticoagulant and dual antiplatelet therapy. During the 1-month postoperative period, patient in the discontinuation and the maintenance antiplatelet group had thromboembolic complication 1 case in each group.

Conclusions: Minor ocular hemorrhage occurred 34% of eyes, with no significant difference between discontinuation and maintenance antiplatelet. There was no significant difference in the incidence of sight threatening hemorrhage and systemic complications.

Keywords: cataract surgery, antiplatelet, anticoagulant, complication.

บทคัดย่อ:

การศึกษาเปรียบเทียบภาวะเลือดออกในตาของผู้ป่วยผ่าตัดต้อกระจกที่ได้รับยาต้านเกล็ดเลือดหรือยาต้านการแข็งตัวของเลือดต่อเนื่อง และแบบหยุดยาก่อนการผ่าตัด

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ผู้นิพนธ์ ไม่มีความเกี่ยวข้องหรือผลประโยชน์กับผลิตภัณฑ์ที่กล่าวถึงในบทความ

วัตถุประสงค์: เพื่อศึกษาเปรียบเทียบภาวะเลือดออกในตาของผู้ป่วยผ่าตัดต้อกระจกที่ได้รับยาต้านเกล็ดเลือดหรือยาต้านการแข็งตัวของเลือดต่อเนื่องและกลุ่มที่หยุดยาก่อนการผ่าตัด

วิธีการวิจัย: เป็นการศึกษาแบบ retrospective cohort ในผู้ป่วยผ่าตัดต้อกระจกของโรงพยาบาลตรังที่ได้รับยาต้านเกล็ดเลือด หรือยาต้านการแข็งตัวของเลือด ระหว่างเดือนมกราคม 2563 ถึงธันวาคม 2563 เปรียบเทียบผู้ป่วย 2 กลุ่ม คือกลุ่มผู้ป่วยที่ได้รับยาต่อเนื่อง และกลุ่มผู้ป่วยที่หยุดยาก่อนการผ่าตัด 5-7 วัน โดยเก็บข้อมูลภาวะเลือดออกในตาและภาวะโรคลิ่มเลือดอุดตันหลังการผ่าตัด 1 วัน, 7 วัน และ 1 เดือน

ผลการวิจัย: ผู้ป่วย 274 คน (288 ตา) เป็นกลุ่มที่หยุดยา 173 ตา กลุ่มที่รับยาต่อเนื่อง 115 ตา จากการศึกษาไม่พบภาวะเลือดออกในตารุนแรงในผู้ป่วยทั้งหมด พบเลือดออกที่เยื่อบุตาขาวในกลุ่มที่หยุดยาต้านเกล็ดเลือดมากกว่ากลุ่มที่ไม่หยุดยาอย่างมีนัยสำคัญทางสถิติ (p=0.01) จากการวิเคราะห์ความสัมพันธ์ของตัวแปรหลายตัว (multivariable analysis) พบว่าสัมพันธ์กับการฉีดยาชา (OR 48.78, 95%CI 18.45-128.97) ไม่สัมพันธ์กับยาต้านเกล็ดเลือด (OR 0.55, 95%CI 0.27-1.11) และพบภาวะโรคลิ่มเลือดอุดตันในกลุ่มที่หยุดยา และได้รับยาต้านเกล็ดเลือดต่อเนื่องกลุ่มละ 1 คน

สรุปผล: พบเลือดออกที่เยื่อบุตาขาวในกลุ่มที่หยุดยาและรับยาต้านเกล็ดเลือดต่อเนื่อง 34% สัมพันธ์กับการฉีดยาชา การรับประทานยาต้านเกล็ดเลือดต่อเนื่องไม่เพิ่มอุบัติการณ์ของการเกิดเลือดออกที่เยื่อบุตาขาว ไม่พบความแตกต่างเรื่องเลือดออกในตารุนแรงและการเกิดลิ่มเลือดอุดตัน

คำสำคัญ: cataract surgery, antiplatelet, anticoagulant, complication

ได้รับอนุมัติจากคณะกรรมการจริยธรรมวิจัยในคน Research ID:003/Study code:02-2564

Introduction

Cataract surgery is one of the most common surgeries performed in elderly patients.[1] Long-term use of anticoagulant or antiplatelet therapy, especially in elderly patients, is becoming increasingly common. More than 28% of these patients take aspirin, 2% take clopidogrel and more than 5% take an anticoagulant.[2] This presents additional challenges in managing those patients requiring cataract surgery. There are risks associated with either stopping or continuing anticoagulant or antiplatelet therapy prior to cataract surgery. If antiplatelet and anticoagulant therapies are continued, there is a risk for serious bleeding complications; however, if these medications are discontinued, there is a risk for thromboembolic complications. A large cohort study has reported that discontinuation of low-dose aspirin results in a 40% increase in the risk of stroke and discontinuing warfarin, risk of stroke increases to 1 in 100.[3] For these reasons, American and European guidelines recommend continuing aspirin and warfarin in the perioperative period, unless the risk of bleeding is clearly higher than the risk of cardiovascular events.[4,5] The 2004 guidelines from the Royal Colleges of Ophthalmologists' in the United Kingdom[6] recommends that patients taking aspirin should continue it before cataract surgery, and patients taking warfarin should continue this medication, but that international normalized ratio (INR) should be within therapeutic level. The American Academy of ophthalmology recommends continuation of anticoagulants in patients undergoing cataract surgery provided that INR is in the therapeutic range. (I+, good quality, strong recommendation) and aspirin be discontinued preoperatively only if the risk of bleeding outweighs its potential benefits. (I-, good quality, strong recommendation).[7] Katz et al. published the results of a large prospective cohort study involving 19,283 cataract surgeries performed at 9 centers in the United States and Canada between June 1995 and June 1997. The authors found that warfarin or aspirin was routinely stopped prior to cataract surgery by 28.3% and 22.5% respectively.[8] The survey in 2003 from Canadian Society of Cataract and Refractive Surgery members found that the majority of ophthalmologist (74.4%) do not stop either warfarin or aspirin for cataract surgery during the perioperative period.[9] However, current practice of many ophthalmologists in Thailand discontinue antithrombotic agents before cataract surgery to reduce sight-threatening bleeding complications such as retrobulbar hemorrhage, suprachoroidal hemorrhage, etc.

The purpose of this study was to compare the incidence of ocular hemorrhage and thromboembolic events perioperatively and postoperatively between patients continuing oral antiplatelet or anticoagulant and those who discontinued them.

Methods

This study comprised consecutive patients taking antiplatelet (ASA, Clopidogrel, Cilostazol) or dual antiplatelet or anticoagulant (warfarin, Dabigatran) who had cataract surgery between January 2020 and December 2020 at Trang Hospital. Exclusion criteria were the patients who having cataract surgery combined with trabeculectomy or pars plana vitrectomy and who did not follow-up at 7 days and 1 month. Patients in the discontinuation group stopped therapy 5-7 days before surgery and resumed therapy the next day postoperatively. Patients who take warfarin

have therapeutic range INR (2-3.5) before surgery and no bridging therapy in discontinuation group. Cataract surgery included phacoemulsification, extracapsular cataract extraction (ECCE), Intracapsular cataract extraction (ICCE) and phacoemulsification with pterygium excision. Phacoemulsification was performed through a clear cornea incision. Anesthesia included topical and local anesthesia (subconjunctival injection or retrobulbar block). The surgeon used 1 method of anesthesia for each patient. After surgery, patients were examined at 1 day, 7 days and 1 month by the surgeon. Intraoperative and postoperative visits, patients were assessed for presence of ocular hemorrhage and thromboembolic complications including cerebral and cardiovascular events. Minor hemorrhagic complications were defined as subconjunctival hemorrhage and hyphema. Retrobulbar hemorrhage and suprachoroidal hemorrhage were sight-threatening hemorrhagic complications. The study protocols were accepted by the IRB of Trang Hospital: Research ID003/Study code:02-2564.

Statistical analysis

Statistical analyses were performed using SPSS version 22. The student t test was used to evaluate continuous variables. Categorical variables were evaluated using the Chi-square test or Fisher exact test. A p-value less than 0.05 was considered statistically significant. Odd ratios were used to quantify association of each variable with causing of ocular hemorrhage. Variables statistically significant in the univariate analysis were included in the multivariable logistic regression model. Data obtained from two eyes of a subject was analysis from one eye only.

Results

Baseline

During the study period, 274 cataract surgery patients (288 eyes) were on antiplatelet or anticoagulant medications. This series represents 19.71% of all cataract surgeries (1,461 eyes) performed at Trang hospital. The number of patients in each group were shown in Table 1. A total of 115 eyes maintained antithrombotic therapy prior to surgery, including 106 eyes (38.7%) continuing antiplatelet, 3 eyes (50%) continuing dual antiplatelet, and 6 eyes (75%) continuing anticoagulant.

Table 1 Oral Antiplatelet and Anticoagulant Medications in Eyes Undergoing Cataract Surgery

Medications	Maintenance (n=eye)	Discontinuation (n=eye)
Antiplatelet		
ASA only	101	147
Clopidogrel only	4	20
Cilostazol (Pletaal)only	1	1
Dual antiplatelet		
ASA+Clopidogrel	2	3
ASA+Cilostazol	1	0
Warfarin	5	2
Dabigatran (Pradaxa)	1	0

Table 2 Demographic characteristics of patients, Types of cataract surgery and Anesthesia

Parameter	Antiplatelet			Dual antiplatelet			Anticoagulant		
	D	M	P-value	D	M	P-value	D	M	P-value
Eye, n	168	106		3	3		2	6	
Sex, n			0.679			1.000			0.429
Male	74	44		2	2		2	2	
Female	94	62		1	1		0	4	
Age, year			0.636			0.606			0.05
Mean ± SD									
Range	70.41 ± 8.08	70.89 ± 8.14		73.33 ± 2.08	71 ± 6.93		66 ± 0.00	77.33 ± 9.22	
	43-86	50-98		71-75	67-79		66	65-87	
Underlying disease									
DM	95	63	0.638	1	2	1.0	0	0	-
HT	144	82	0.102	2	3	1.0	1	3	1.000
Dyslipidemia	117	82	0.163	0	3	0.1	2	3	0.464
Heart disease	38	28	0.474	2	1	1.0	2	6	0.157
Stroke	64	31	0.134	3	2	1.0	0	4	0.429
Type of Surgery, n			0.473			1.000			1.000
Phaco+IOL	160	99	3	3		2	5		
ECCE+IOL	6	4	-	-		0	1		
ICCE+IOL	1	0	-	-		-	-		
Phaco+IOL+ Pterygium excision	1	3	-	-		-	-		
Anesthesia, n									
Topical	81	57	0.041	2	2	1.000	0	4	0.046
Subconjunctival	61	22	< 0.001	1	1	1.000	2	1	0.564
Injection									
Retrobulbar block	26	27	0.891	0	0	-	0	1	0.317

D = discontinuation group, M= maintenance group

Table 2 shows patients' demographic data, types of cataract surgery and anesthesia by group. There was no statistically significant difference in age, sex, or underlying diseases between the maintenance group and the discontinuation group.

Phacoemulsification was the most performed cataract surgeries. There were not statistically different concerning types of cataract surgery between the maintenance and the discontinuation group. Topical anesthesia, subconjunctival anesthesia and retrobulbar block were performed 138 patients (50.7%), 83 patients (30.5%), and 53 patients (18.8%) respectively. All eyes of ECCE and ICCE were performed by retrobulbar block.

The discontinuation antiplatelet group used topical and subconjunctival anesthesia more than the maintenance group with statistically significant ($p = 0.041$, $p < 0.001$ respectively).

There was no difference in type of anesthesia comparing the maintenance dual antiplatelet and the discontinuation group. However, regarding patients who used anticoagulant, the maintenance group

applied topical anesthesia technique more than the discontinuation group (p = 0.046).

Complications

Table 3 shows the incidence of ocular hemorrhage and systemic complications. The incidence of subconjunctival hemorrhage was significantly higher in the discontinued antiplatelet group than in the maintenance group (P = 0.010). Hyphema, retrobulbar hemorrhage and suprachoroidal hemorrhage were not found.

To further analysis the associations between the predictor variable for subconjunctival hemorrhage in antiplatelet used patients, 3 eyes were excluded in analysis because they were 2nd eye. Maintenance antiplatelet, type of cataract surgery (cataract surgery with conjunctival excision) and sharp-needle ophthalmic anesthesia were statistically significant in univariate analysis then multivariable logistic regression were conducted in Table 4. The maintenance

Table 3 Incidence of complications by group

Complication	Antiplatelet			Dual antiplatelet			Anticoagulant		
	D (n=168)	M (n=106)	P-value	D (n=3)	M (n=3)	P-value	D (2)	M (6)	P-value
Ocular hemoorrhage									
- Subconjunctival hemorrhage	68 (40.5%)	25 (24.5%)	0.010	1 (33.3%)	1 (33.3%)	1.0	1 (50%)	2 (33.3%)	1.00
- Hyphema	0	0		0	0	-	0	0	-
- Retrobulbar hemorrhage	0	0		0	0	-	0	0	-
- Suprachoroidal hemorrhage	0	0		0	0	-	0	0	-
Thromboembolic			1.00			-			-
Complication									
- Myocardial infarction	1	0		0	0		0	0	
- Stroke	0	1		0	0		0	0	

D = discontinuation group, M = maintenance group

Table 4 Multivariable association of antiplatelet, block and type of cataract surgery with subconjunctival hemorrhage

Factor	Odds ratio	95% confident interval	P-value
Maintenace antiplatelet	0.55	0.27-1.11	0.094
Sharp needle local anesthesia (subconjunctival block, retrobulbar block)	48.78	18.45-128.97	< 0.001
Cataract surgery with excision conjunctiva (ECCE, ICCE, phaco with pterygium excision)	8.54	1.07-67.99	0.043

or discontinued antiplatelet in cataract surgery had the same chance of subconjunctival hemorrhage with OR of 0.55 (95%CI 0.27-1.11, p = 0.094). Variables that significantly increased risk of subconjunctival hemorrhage were subconjunctival and retrobulbar block (OR 48.78, 95%CI 18.45-128.97, p < 0.001) and cataract surgery with conjunctival excision (OR 8.54, 95%CI 1.073-67.986, p = 0.043). The dual antiplatelet and anticoagulant group, the number of cases had too small for risk stratification.

Systemic complications occurred in 2 patients. The first patient from the discontinuation antiplatelet group had sudden cardiac arrest due to myocardial infraction 2 days after surgery, the other one patient from the maintenance antiplatelet group had recurrent stroke on day 20th after surgery. For dual antiplatelet and anticoagulant therapy, there was no significant difference between the maintenance group and the discontinuation group in the incidence of perioperative or postoperative ocular hemorrhage and systemic complications.

Discussion

In this study, patients who continued taking antiplatelet or anticoagulant showed no increase in the incidence of sight-threatening ocular hemorrhages. Although, the incidence of subconjunctival hemorrhage was significantly greater in the discontinuation group, this resulted from sharp needle local anesthesia. Multivariate analysis showed that maintenance or discontinued antiplatelet has the same chance of subconjunctival hemorrhage. The significant independent risk factors were sharp needle local anesthesia and cataract surgery with conjunctival excision. Serious hemorrhagic complications from local anesthesia are very uncommon. This study does not have sufficient statistic power to draw conclusions about the incidence of potentially sight-threatening hemorrhagic local anesthesia complications in patients on antiplatelet or anticoagulant.

Ophthalmic anesthesia

Local ophthalmic anesthesia techniques include needle-based (intraconal retrobulbar, extraconal peribulbar, subconjunctival) or canula-based (sub-Tenon's) blocks. Hemorrhagic complications include retrobulbar hemorrhage (major) and subconjunctival hemorrhage (minor). Data from a survey in 2004 showed that ophthalmologists in Thailand still used retrobulbar block in 30.3% of phacoemulsification, 62.7% of extracapsular cataract extraction, and 81.1% of intracapsular cataract extraction.[10] Incidence of retrobulbar hemorrhage after retrobulbar block in Thailand is 2.2%.[11] Severe complications occur more frequently in elderly patients and recent use of anticoagulants but retrobulbar hemorrhage was not found in this study. The risk of retrobulbar hemorrhage in patients taking antithrombotic remains controversial, with the reported incidence ranging from 0.016-1.7%. A prospective study in 1,383 patients concluded that the preoperative use of aspirin or warfarin whether or not they had been discontinued, did not predispose to hemorrhage associated with retrobulbar block.[12] Benzimra et al.[2] reported on 48,862 patients in the Cataract National Dataset, the patients had significant increase in subconjunctival hemorrhage with clopidogrel (4.4%) and warfarin (3.7%) compared to non-antithrombotic users (1.7%) who had sub-Tenon's or sharp needle anesthesia. In contrast, the case series involved 19,283 cataract surgeries didn't show an

increased risk of medical and ophthalmic hemorrhagic complications during local anesthesia or cataract surgery in routine anticoagulant or antiplatelet use.13 A recent systematic review using stricter inclusion criteria concluded that none of the studies revealed significant bleeding related to needle-based blocks when concurrent aspirin, clopidogrel, or warfarin was administered.[14] However, A retrospective study of 160,000 patients who received retrobulbar or peribulbar anesthesia reveals that 3 patients developed a grade IV retrobulbar hematoma (sight-threatening). Of these 3 cases, 1 patient was on dual antiplatelet therapy, 1 was on warfarin, and 1 was on a combination of dual antiplatelet and warfarin therapy.[15] Therefore Royal college of ophthalmologist and British society of Hematology recommended routine cataract surgery under topical or sub-Tenon's anesthesia would be to continue all antithrombotic agents. This contrasts with patients on dual antiplatelet therapy, who may have an increased risk of sight-threatening hemorrhagic complication. This is due to hemorrhagic risks associated with the block rather than the cataract itself.[16] Risk reduction of hemorrhage can achieved with topical anesthesia, which is the most appropriate way for experienced surgeons who can operate on mobile eyes, and for patients who cooperate well while undergoing surgery.

Cataract surgery

Cataract surgeries are considered low risk procedures.[16] Phacoemulsification for cataract surgery is nowadays the standard of care, and significant bleeding is exceedingly rare, even in patients receiving antithrombotic therapy. However, concerns exist when large incision extracapsular cataract extractions are performed because this surgery has been associated with increased risks of hyphema and suprachoroidal hemorrhage. The incidence of suprachoroidal hemorrhage during cataract surgery ranges from 0.03% in phacoemulsification to 0.13% in extracapsular cataract extractions. The main risk factors for expulsive hemorrhage are advance age, arteriosclerosis, diabetes, hypertension, and local eye conditions (high myopia, glaucoma, recent surgery, choroidal sclerosis).[17] A meta-analysis of 11 studies involving cataract surgery in patients on warfarin reported an increased incidence of minor and self-limiting hemorrhage (hyphema, subconjunctival hemorrhage).[18] The result in several studies show that maintaining an antiplatelet and/or anticoagulant therapy during the perioperative period does not significantly increase the incidence of the potentially sight-threatening complications associated with phacoemulsification.[19]

Thromboembolic complications

Thromboembolic complications were reported in 2 cases of this study. There was one death from myocardial infarction in the discontinued antiplatelet group. The other one from the maintained antiplatelet group had recurrent stroke. There was some evidence for increased risk of myocardial ischemia and stroke among routine users of aspirin or warfarin who continued to use these before surgery, compared with those who were not routine users. This increased risk is likely explained by the higher prevalence of pre-existing comorbidities among routine aspirin and warfarin users.

A systematic review by Dunn and Turpin found no significant difference in thromboembolic event rates between different perioperative management

strategies.[20] In contrast with a large study investigated the risk of complications from the perioperative use of anticoagulant in 19,283 patients found that the rate of thrombotic complications was much higher on interruption of anticoagulants than the rate of bleeding complications on continued used.[13] Although the incidence is small but when an event did occur, it was much more serious and led to a significant increase in morbidity and mortality.

The data from this study support the continued use of antiplatelet and anticoagulant agents among routine users because the risk of sight threatening ocular hemorrhage was not increased, even with continuing these medications.

The current study has several limitations. The design was non-randomized, and the sample size was small, the analytical power was not great enough to detect small differences that might have been present. Especially, the numbers of patients on dual antiplatelet or anticoagulant were small. Therefore, clinical application is limited, particularly rare complications. The large sample of randomized controlled trials would be required to determine the safety of continuous antiplatelet and anticoagulant therapy associated with cataract surgery. But randomization is not feasible for these types of studies, as purposeful discontinuation of antithrombotic would unethically raise the risk of thrombotic events.

Conclusions

The results in our study did not found the sight threatening ocular hemorrhage in antithrombotic used patients. We found only minor ocular hemorrhage (34%) that associated with sharp needle local anesthesia and larger excision of cataract surgery. The maintenance antiplatelet did not increase the bleeding risk. If it appears that antiplatelet or anticoagulant drugs should be discontinued preoperatively, consultation from the surgeon with the patient's attending physicians and multi-disciplinary team is needed. Discussion with patients and their relatives concerning consequences of ocular hemorrhages and risks of thromboembolic events is crucial.

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