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Cessation or Continuation of Aspirin in Patients Undergoing 20-gauge Pars Plana Vitrectomy due to Diabetic Retinopathy

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Abstract

Background: This study aimed to evaluate the incidence of ocular hemorrhages in patients with proliferative diabetic retinopathy (PDR) undergoing 20-gauge pars plana vitrectomy (PPV) taking aspirin as an antiplatelet agent versus those who did not take any aspirin. **Materials and Methods:** A total of 180 patients (mean age of 60.5 ± 9.9 years) with PDR referred to Baqiyatallah University Hospital in 2016 were enrolled in aspirin and control groups each group containing 90 patients. All participants underwent a standard 20-gauge diabetic PPV. Laboratory data, including fasting blood sugar, prothrombin time, partial thromboplastin, bleeding time, and platelets count, and intraoperative data, including bleeding and its type (retinal, subretinal, vitreous, conjunctival, sub-conjunctival, and hyphema), were collected and analyzed using SPSS16 software. **Results:** Bleeding occurred in 56 patients. There were no significant differences in the incidence of bleeding between aspirin (33 patients) and control groups (23 patients) (P= 0.1). Likewise, no significant differences were observed in the type of bleeding between the two groups (P= 0.11). Age, gender, hypertension, type of operation, and laboratory findings were not significant between patients with and without bleeding.**Conclusion:** The results of this study indicated that taking aspirin is not associated with a higher risk of post-PPV surgery bleeding in comparison with the control group. Additionally, the type of bleeding did not significantly differ between the two groups. Hence, there is no urgent need for discontinuation of this medication in diabetic patients undergoing PPV.**[GMJ.2017;6(2):95-101] DOI: 10.22086/GMJ.V6I2.763**

Keywords: Aspirin; Diabetic Retinopathy; Eye Hemorrhage; Vitrectomy

Introduction

Antiplatelet therapy is a common prophylactic treatment in patients with different risk factors for cardiovascular diseases, including patients with diabetes mellitus (DM) [1]. The prevalence of DM due to lifestyle and other causes is on the rise. Diabetic retinopathy is one of the major complications of DM and its prevalence increases with the continuation of disease [2]. Despite various medical treatments, nearly 5% of patients with diabetic retinopathy eventually require surgical intervention.

Pars plana vitrectomy (PPV) is commonly used for these patients. Many of these patients,

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due to DM and its related complications, are on prophylactic anticoagulation/antiplatelet therapy. Therefore, management of these patients before surgery is an important challenge for ophthalmologists. Discontinuation of aspirin or warfarin in patients who undergo ocular surgery depends on post- and intraoperative indications.

One of the most important complications following vitrectomy is pre- and postoperative vitreous cavity hemorrhage (VCH). Attention to increasing risk of cardio- and cerebrovascular complications due to the discontinuation of mentioned drugs is another important issue [3, 4]. The incidence of postoperative hemorrhage in diabetic patients after vitrectomy has been reported between 12 and 63% [5, 6]. Several studies have investigated the risks of cessation versus continuation of anticoagulation/antiplatelet drugs for intraocular surgeries. Some of these studies suggest that preoperative continuation of these drugs do not increase the risk of intra-operative or postoperative VCH [7-9]. While other studies report that sight-threatening bleeding complications are more frequent in patients on antiplatelet regimens than those on anticoagulant agents [9]. There are only a handful of studies on diabetic patients, however; one such study reports that anticoagulation or antiplatelet treatment can be safely continued preoperatively in patients undergoing diabetic vitrectomy [7], whereas another study indicates that preoperative continuation of such drugs increases the risk of persistent postoperative VCH in diabetic patients [10].

Another factor that seems to affect postoperative VCH is related to PPV and small-incision PPV instrumentation. Although benefits of 25-gauge PPV over the standard 20-gauge PPV have been reported, Lee and Yu found a similar incidence of postoperative VCH in 25-gauge PPV compared to 20-gauge PPV in patients with proliferative diabetic retinopathy (PDR) [11]. It has also been shown that both methods of 23-gauge PPV and 20-gauge PPV in patients with PDR have the same rate of success [12]. In a retrospective chart review, the authors assessed the rate of 25-gauge PPV hemorrhagic complications in patients with the perioperative continuation of anticoagulation or platelet inhibitor therapy [13]. They observed that the rate of hemorrhagic complications is considerably low.

To the best of our knowledge, to date, no study has estimated the risk of hemorrhagic complications associated with 20-gauge PPV in PDR patients who were receiving aspirin as an antiplatelet drug preoperatively. Thus, the aim of this study was to compare the incidence of ocular hemorrhages in patients with PDR who were taking aspirin as antiplatelet agent undergoing 20-gauge PPV to the control group.

Materials and Methods

Setting

Between March 2016 and August 2016, 180 patients with diabetic proliferative retinopathy referring to Baqiyatallah University Hospital were examined.

Study Design

In this prospective cohort study, 180 patients (eyes) referred to Baqiyatallah University Hospital between March and August 2016 were evaluated. Nineteen patients were taking aspirin, from different companies, (80mg tablets per day), and 90 patients did not take aspirin.

A standard 20-gauge vitrectomy was performed on all eyes and for treating the peripheral retina up to ora serrate, an endolaser photocoagulation (Bausch+Lomb Company) used in all cases. During the operation, for patients with definite or suspected holes, intraocular gas, silicone or Avastin (Rosche Company, Switzerland) were applied. Patients in the aspirin group did not have any modification in their treatment before and after surgery.

Inclusion Criteria

Diabetic patients who had retinopathy due to traction macular detachment, peri macular hemorrhage and other unknown viteral hemorrhages and from them those who were taking 80 mg aspirin tablets for at least 30 days included to the study.

Exclusion Criteria

Patients with any changes in aspirin regimen

or use of any other antiplatelets or anticoagulations treatment were excluded from this project. Moreover, patients that needed PPV for any other indications, like chronic diabetic macular edema and epiretinal membrane, were not included in this study.

Data Collection

Demographic data including age and gender; laboratory data, including fasting blood sugar (FBS), prothrombin time (PT), partial thromboplastin (PTT), bleeding time (BT), and platelets count; and intraoperative data including bleeding and its type (retinal, subretinal, vitreous, conjunctival, sub-conjunctival, and hyphema), were collected. The occurrence of the bleeding and its type detected by an ophthalmologist. Also, the existence of hypertension (HTN) (systolic blood pressure≥140mmhg and diastolic blood pressure≥90mmhg) as an underlying disease was investigated in all participants.

Ethical Considerations

This study was approved by the Ethics Committee of Baqiyatallah University (Ref. No: IR.BMSU.REC.1394.178). All participants signed an informed written consent before enrollment in the study.

Data Analysis

The SPSS 16.0 (SPSS Inc, Chicago, Illinois, United States) was used for data analysis. Quantitative and qualitative variables were presented as the mean ± standard deviation (SD) and frequency, respectively. Differences between aspirin and control groups were examined by independent t-test and Chi-square for qualitative and quantitative variables, respectively. A P-values less than 0.05 were considered significant. The binary logistic regression was also used for comparing the two groups considering the effect of all other variables.

Results

A total of 180 patients (82 male and 98 female) undergoing 20-gauge diabetic PPV surgery with the mean age of 60.5 ± 9.9 years were evaluated. There were no significant differences in demographic data between the two groups (P> 0.05). The mean duration of aspirin consumption was 35.75 ± 36.43 months, and the last aspirin dose was consumed 18.48 ± 13.49 hours before surgery. The HTN was significantly higher in the aspirin group compared with the control group (57 and 32, respectively) (P < 0.001). There was no significant difference in the type of operation between the two groups (P= 0.19). More detailed descriptions of the patients are presented in Table-1. The FBS was significantly higher in the aspirin group in comparison to the control group (164 and 139 mg/dL, respectively) (P= 0.03). There were no significant differences in other laboratory findings between the two groups (P > 0.05).

Table 1. Patients' Characteristics

Variables	Study Groups		P value
	Aspirin (n = 90)	Control (n = 90)	
Age, years	61.4 ± 9.4	59.5 ± 10.5	0.20
Male gender, N (%)	40 (44.4)	42 (46.7)	0.76
Underlying diseases			< 0.00
Diabetes	33 (36.7)	58 (64.4)	
Diabetes + HTN	57 (63.3)	32 (35.6)	
Type of operation			0.19
PPV* + Endolaser + Membranectomy + Silicone	29 (32.2)	37 (41.1)	
PPV* + Endolaser + Membranectomy + Avastin	18 (20)	16 (17.8)	
PPV* + Endolaser + Avastin	37 (41.1)	36 (40)	
PPV* + Endolaser + Gas	6 (6.7)	1 (1.1)	

* Pars Plana Vitrectomy

Bleeding occurred in 56 patients. There was no significant difference in the incidence of bleeding between the two groups (33 and 23, respectively) (P= 0.10). There was not a significant difference in the type of bleeding between the two groups (P = 0.11). Laboratory findings and the incidence of bleeding occurrence and its types are described in Table-2.
There were also no significant differences between patients with and without bleeding regarding age, gender, HTN, type of operation, and laboratory findings. Comparison of patients with and without bleeding is presented in Table-3.
The multivariable regression analysis also showed no significant difference between the two groups (P=0.88).

Table 2. Comparison of Laboratory Findings After Operation Between the Two Groups

Laboratory	Study Groups		P-value
	Aspirin (n = 90)	Control (n = 90)	
Fasting blood sugar	164.8 ± 81.1	139.7 ± 72.5	0.03
Platelet Count	258.8 ± 69.8	278.3 ± 76.1	0.07
PT*	12.53 ± 0.84	12.58 ± 0.69	0.70
PTT†	31.72 ± 2.9	30.87 ± 4.0	0.11
BT‡	2.26 ± 0.71	2.16 ± 0.56	0.31
No Bleeding	57 (63.3)	67 (74.4)	0.10
Bleeding	33 (36.7)	23 (25.6)	
Type of bleeding			0.11
Retinal	6 (6.7)	13 (14.4)	
Subretinal	0 (0)	2 (2.2)	
Vitreous	2 (2.2)	10 (11.1)	
Conjunctival	3 (3.3)	5 (5.6)	
Sub-conjunctival	13 (14.4)	10 (11.1)	
Hyphema	1 (1.1)	0 (0)	

* Bleeding Time; † Prothrombin Time; ‡ Partial Thromboplastin

Table 3. Comparison of Patients with and without Bleeding

Variables	Bleeding		P- value
	Yes (n = 56)	No (n = 124)	
Age, years	61.1 ± 8.7	60.2 ± 10.5	0.56
Male gender, N (%)	24 (42.9)	58 (46.8)	0.62
Hypertension	34 (60.7)	55 (44.4)	0.04
Type of operation			0.32
PPV* + Endolaser + Membranectomy + Silicone	22 (39.3)	44 (35.5)	
PPV* + Endolaser + Membranectomy + Avastin	10 (17.9)	24 (19.4)	
PPV* + Endolaser + Avastin	24 (42.9)	49 (39.5)	
PPV* + Endolaser + Gas	0 (0)	7 (5.6)	
Fasting blood sugar	160.6 ± 94.7	148.5 ± 68.8	0.33
Platelet Count	256.9 ± 70.7	273.8 ± 74.4	0.15
PT†	12.46 ± 0.73	12.59 ± 0.78	0.28
PTT‡	31.68 ± 3.6	31.12 ± 3.5	0.32
BT‡‡	2.08 ± 0.49	2.27 ± 0.69	0.06

* Pars Plana Vitrectomy; † Prothrombin Time; ‡ Partial Thromboplastin; ‡‡ Bleeding Time

Discussion

The results of this study showed that taking aspirin is not associated with a higher risk of post 20-gauge PPV surgery bleeding. The type of bleeding was not significantly different between aspirin and control groups.

Except for a significantly higher level of FBS in the aspirin group, there were no significant differences in other laboratory findings between the two groups.

Demographic data, the prevalence of HTN, type of operation, and laboratory findings were not significantly different between patients with and without postoperative bleeding.

In a retrospective cohort study, comparing hemorrhagic complications of warfarin and clopidogrel in 25-gauge PPV versus a control group, Mason *et al*. concluded that the risk of hemorrhagic complications in patients who underwent systemic anticoagulation or antiplatelet therapies is dramatically low. They also recommended the continuation of these therapies in patients undergoing 25-gauge PPV considering the risk associated with cessation [13], which is in concordance with the results of the present study despite using a 20-gauge needle probe for PPV which is thicker than 25-gauge and is expected to be logically associated with more bleeding complications.

In another study, Dayani *et al*. [14] assessed the maintenance of anticoagulation therapies in patients undergoing vitreoretinal surgery and reported significantly low postoperative hemorrhagic complications in patients with therapeutic levels of Warfarin anticoagulation. They stated that discontinuation of anticoagulant therapies should be individualized based on patients' medical history and surgical procedure.

Passemard *et al*. [9] made the same recommendation as they found some slight-threatening bleeding complications following vitreoretinal surgery by peribulbar anesthesia in patients on antiplatelet agents.

In another retrospective cohort study by Brown *et al*. [7], patients on anticoagulation therapy who underwent PDR were evaluated for the risk of perioperative hemorrhage. They demonstrated that these patients do not present a higher risk of intraoperative or postoperative VCH. They also suggested the continuation of anticoagulants therapy to avoid complications due to the underlying disease.

Fabinyi *et al*. [10] evaluated the effect of perioperative anticoagulation and antiplatelet therapies on the risk of postoperative VCH in patients undergoing PPV for diabetic diseases. They reported that continuation of anticoagulant or antiplatelet therapies is associated with a higher risk of VCH, which requires additional surgery. They mentioned that clinicians must balance the risk of withdrawal and continuation of these therapies considering the risk of thromboembolic events and systemic disease. According to them, cessation of anticoagulants in low-risk patients may lower the risk of VCH, though, in high-risk patients, treatment should be continued.

Evaluating the effects of aspirin and warfarin therapies on the incidence of hemorrhagic complications in vitreoretinal surgery, Narendran *et al*. concluded that anticoagulation is not significantly associated with higher risk of perioperative hemorrhages.

They reported that warfarin is associated with bleeding complications more than aspirin. Therefore, they suggested the discontinuation of warfarin in low-risk patients and added that for these patients circumstances should be considered individually. They did not see any advantage in aspirin discontinuation prior to surgery which is in agreement with the findings of the present study [15]. The results of similar studies are briefly reviewed in Table-4.

Conclusion

Taking aspirin is not associated with a higher risk of post-PPV. Additionally, the type of bleeding did not significantly differ between the two groups. Hence, there is no urgent need for discontinuation of this medication in diabetic patients undergoing PPV.

Conflict of Interest

There were no conflicts of interest for the present study.

Table 4. Brief Review of Similar Studies

Author(s)	Publication Year	Evaluated Drug(s)	Type of Surgery	Conclusion
Narendran *et al.* [15]	2003	Aspirin & Warfarin	Vitreoretinal	Continuation recommended for Aspirin and Cessation for Warfarin
Chauvaud *et al.* [16]	2006	Anticoagulants & Antiplatelet	Vitreoretinal	Continuation recommended
Dayani *et al.* [14]	2006	Warfarin	Vitreoretinal	Continuation recommended
Fu *et al*. [8]	2007	Warfarin	Vitreoretinal	Cessation is not necessary
Tan *et al.* [17]	2009	Anticoagulants & Antiplatelet	Vitreoretinal	Modification of Drugs in selected cases recommended
Chandra *et al.* [18]	2010	Warfarin	PPV	Continuation recommended
Mason *et al.* [13]	2011	Warfarin & Clopidogrel	25-Gauge PPV	Continuation recommended
Brown *et al.* [7]	2011	Anticoagulants	Diabetic vitrectomy	Continuation recommended
Fabinyi *et al.* [10]	2011	Anticoagulants & Antiplatelet	Diabetic PPV	Cessation Recommended
Lip *et al.* [19]	2011	Aspirin & Warfarin	Most ophthalmic procedures	Continuation recommended
Oh *et al*. [20]	2011	Anticoagulants & Antiplatelet	Vitreoretinal	Continuation recommended
Passemard *et al.* [9]	2012	Anticoagulants & Antiplatelet	Vitreoretinal	Continuation recommended
Bonhomme *et al.* [21]	2013	Anticoagulants & Antiplatelet	Most ophthalmic procedures	Continuation recommended
Donaldson *et al.* [22]	2013	Anticoagulants	Vitreoretinal	Continuation recommended
Gallice *et al.* [23]	2015	Anticoagulants & Antiplatelet	Vitreoretinal	Continuation recommended for antiplatelet and for anticoagulants with INR<3
Current study	--	Antiplatelet (Aspirin)	20-gauge PPV	Continuation recommended

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