# Safety and Necessity of Antiplatelet Therapy on Patients Underwent Endovascular Aortic Repair with Both Stanford Type B Aortic Dissection and Coronary Heart Disease

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## Abstract

**Background:** Acute aortic dissection is known as the most dangerous aortic disease, with management and prognosis determined as the disruption of the medial layer provoked by intramural bleeding. The objective of this study was to evaluate the safety and necessity of antiplatelet therapy on patients with Stanford Type B aortic dissection (TBAD) who underwent endovascular aortic repair (EVAR).

**Methods:** The present study retrospectively analyzed 388 patients with TBAD who underwent EVAR and coronary angiography. The primary outcomes were hemorrhage, death, endoleak, recurrent dissection, myocardial infarction, and cerebral infarction in patients with and without aspirin antiplatelet therapy at 1 month and 12 months.

Results: Of those 388 patients, 139 (35.8%) patients were treated with aspirin and 249 (64.2%) patients were not treated with aspirin. Patients in the aspirin group were elderly (57.0  $\pm$  10.3 years vs. 52.5  $\pm$  11.9 years, respectively,  $\chi^2 = 3.812$ , P < 0.001) and had more hypertension (92.1% vs. 83.9%, respectively,  $\chi^2 = 5.191$ , P = 0.023) and diabetes (7.2% vs. 2.8%, respectively,  $\chi^2 = 4.090$ , P = 0.043) than in the no-aspirin group. Twelve patients (aspirin group vs. no-aspirin group; 3.6% vs. 2.8%, respectively,  $\chi^2 = 0.184$ , P = 0.668) died at 1-month follow-up, while the number was 18 (4.6% vs. 5.0%, respectively,  $\chi^2 = 0.027$ , P = 0.870) at 12-month follow-up. Hemorrhage occurred in 1 patient (Bleeding Academic Research Consortium [BARC] Type 2) of the aspirin group, and 3 patients (1 BARC Type 2 and 2 BARC Type 5) in the no-aspirin group at 1-month follow-up ( $\chi^2 = 0.005$ , P = 0.944). New hemorrhage occurred in five patients in the no-aspirin group at 12-month follow-up. Three patients in the aspirin group while five patients in the no-aspirin group had recurrent dissection for endoleak at 1-month follow-up (2.3% vs. 2.2%, respectively,  $\chi^2 = 0.074$ , P = 0.816). Four patients had new dissection in the no-aspirin group at 12-month follow-up (2.3% vs. 3.8%, respectively,  $\chi^2 = 0.194$ , P = 0.660). Each group had one patient with myocardial infarction at 1-month follow-up (0.8% vs. 0.4%, respectively,  $\chi^2 = 0.102$ , P = 0.749) and one more patient in the no-aspirin group at 12-month follow-up. No one had cerebral infarction in both groups during the 12-month follow-up. In the percutaneous coronary intervention (PCI) subgroup, 44 (31.7%) patients had taken dual-antiplatelet therapy (DAPT, aspirin + clopidogrel) and the other 95 (68.3%) patients had taken only aspirin. There was no significant difference in hemorrhage (0% vs. 1.1%, respectively,  $\chi^2 = 0.144$ , P = 0.704), death (4.8% vs. 4.5%, respectively,  $\chi^2 = 0.154$ , P = 0.695), myocardial infarction (2.4% vs. 0%, respectively,  $\chi^2 = 0.144$ , P = 0.704), endoleak, and recurrent dissection (0% vs. 3.4%, respectively,  $\chi^2 = 0.344$ , P = 0.558) between the two groups at 12-month follow-up.

**Conclusions:** The present study indicated that long-term oral low-dose aspirin was safe for patients with both TBAD and coronary heart disease who underwent EVAR. For the patients who underwent both EVAR and PCI, DAPT also showed no increase in hemorrhage, endoleak, recurrent dissection, death, and myocardial infarction.

Key words: Acute Coronary Syndrome; Antiplatelet; Aortic Dissection; Endovascular Aortic Repair

## INTRODUCTION

Acute aortic dissection is known as the most dangerous aortic disease,<sup>[1-3]</sup> with management and prognosis

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Received: 14-05-2017 Edited by: Li-Min Chen How to cite this article: He RX, Zhang L, Zhou TN, Yuan WJ, Liu YJ, Fu WX, Jing QM, Liu HW, Wang XZ. Safety and Necessity of Antiplatelet Therapy on Patients Underwent Endovascular Aortic Repair with Both Stanford Type B Aortic Dissection and Coronary Heart Disease. Chin Med J 2017;130:2321-5. determined as the disruption of the medial layer provoked by intramural bleeding. Stanford Type A aortic dissection should be treated with urgent surgical intervention, whereas Stanford Type B aortic dissection (TBAD) could be treated with endovascular aortic repair (EVAR) or medical treatment.<sup>[4]</sup> TBAD patients always combined with coronary heart disease (CHD). These patients may require PCI after EVAR or require necessary anticoagulant and antiplatelet therapies.<sup>[5]</sup> However, anticoagulant and antiplatelet therapies in patients with aortic dissection might lead to consequences such as rupture of the aortic wall and bleeding complications.<sup>[6]</sup> Previous studies showed that chronic anticoagulation therapy can increase the incidence of reintervention and endoleak in patients with TBAD and CHD.<sup>[7]</sup> Other studies have showed a significant increase of ischemic events in patients with TBAD and CHD without antiplatelet therapy after EVAR.<sup>[8-10]</sup> Therefore, it was an unsolved problem whether antiplatelet therapy should be used in patients with TBAD and CHD. The present study aimed at evaluating the safety and necessary of antiplatelet therapy for TBAD treated with EVAR combined with CHD.

# **M**ethods

## **Ethical approval**

This study was approved by the Medical Ethics Committee of General Hospital of Shenyang Military Region, China (No.[2016] 93).

## **Study population**

A total of 388 consecutive patients who underwent EVAR for TBAD were recruited from January 2007 to August 2014 at General Hospital of Shenyang Military Region. All patients were diagnosed by aortic angiography. Inclusion criteria were as follows: (1) Patients with TBAD combined with aortic aneurysm; (2) patients with successfully implanted aortic graft with TBAD; and (3) patients with TBAD who underwent coronary angiography. Patients with aortic disease would be excluded if they met the following criteria for EVAR: (1) Patients diagnosed as explicitly Stanford Type A aortic dissection, penetrating aortic ulcers, trauma dissection, pseudo aneurysm, intramural hematoma, aortic aneurysm, and Marfan syndrome; (2) patients with TBAD after Stanford Type A aortic dissection (such as Marfan syndrome) of postsurgery; (3) recurrence in patients with Stanford B aortic dissection needed to treat with EVAR again; (4) patients with previous myocardial infarction and severe heart, liver, and renal insufficiency inhibition for aortic angiography examination; (5) patients with the severity of bleeding disorders recently or active bleeding; (6) patients associated with serious basis diseases; and (7) patients allergic to contrast agents.

## Study design

The patients were divided into two groups according to whether the application of antiplatelet drugs into two groups.

The characteristics of patients treated with aspirin (139 cases) for at least one coronary artery stenosis  $\geq$ 50% with one or more risk factors were as follows: aging  $\geq$ 45 years in males and >50 years in females, hypertension, hyperlipidemia, diabetes, and coronary angiography performed before EVAR deployment. Among them, 44 patients underwent PCI 3 days to 3 months after EVAR. All of them were treated with clopidogrel for 1 year. Patients whose coronary artery angiography stenosis <50% or coronary artery stenosis  $\geq$ 50% without risk factor mentioned before were not treated with aspirin (249 cases).

## **End point**

Primary outcomes for the study were incidence of hemorrhage (based on the BARC classification), death (cardiac death, aortic cardiac death, and other reasons of death), endoleak, recurrent dissection, myocardial infarction, and cerebral infarction in patients with or without antiplatelet therapy at 1 month and 12 months.

## Follow-up

Follow-up was performed on all patients after discharge until the end of the study period in September 2015 using a combination of direct patient contact, telephone interview, and referring physician contact. The patients were followed up at 1<sup>st</sup> month, 6<sup>th</sup> month, 1 year, and then annually after the procedure. Patients' blood pressure, use of medication, general physical condition, and outcomes were recorded.

## **Statistical methods**

Comparisons between continuous variable data, expressed as mean  $\pm$  standard deviation (SD), were performed with the *t*-test, while the Chi-square or the Fisher's exact tests were used for categorical data, expressed as percentages. Statistical analyses were performed with the SPSS version 20.0 software (SPSS Inc., Chicago, Illinois, USA). A two-sided P < 0.05 was considered statistically significant.

# RESULTS

# **Baseline characteristics**

A total of 388 patients were enrolled in this study, of whom 139 (35.8%) patients were treated with aspirin and 249 (64.2%) patients were not treated with aspirin. Baseline characteristics of the two groups were summarized in Table 1. Patients in the aspirin group were elder than those in the no-aspirin group (57.0 ± 10.3 years vs. 52.5 ± 11.9 years, respectively, t = 3.812, P < 0.001). More patients had a history of hypertension (92.1% vs. 83.9%, respectively,  $\chi^2$  = 5.191, P = 0.023) and diabetes (7.2% vs. 2.8%, respectively,  $\chi^2$  = 4.090, P = 0.043) in the aspirin group than those in the no-aspirin group. There were more patients using statins in the aspirin group than no-aspirin group (52.5% vs. 21.7%,  $\chi^2$ = 38.511, P < 0.001). Other baseline characteristics showed no significant differences between the two groups.

## **Clinical outcomes**

Twelve patients died during the 1-month follow-up, of whom 5 (3.6%) patients were treated with aspirin and 7 (2.8%)

Items	Aspirin group ( $n = 139$ )	No-aspirin group ( $n = 249$ )	t or $\chi^2$	Р
Age (years)	57.0 ± 10.3	52.5 ± 11.9	3.812*	< 0.001
Male, <i>n</i> (%)	114 (82.0)	196 (78.7)	0.605	0.437
Smoker, <i>n</i> (%)	79 (56.8)	158 (63.5)	1.644	0.200
Drinker, <i>n</i> (%)	47 (36.4)	96 (38.6)	0.162	0.687
Hypertension, n (%)	128 (92.1)	209 (83.9)	5.191	0.023
Diabetes, $n$ (%)	10 (7.2)	7 (2.8)	4.090	0.043
Cerebrovascular diseases				
Hemorrhage, $n$ (%)	2 (1.4)	8 (3.2)	0.523	0.470
Ischemia, n (%)	18 (12.9)	20 (8.0)	2.442	0.118
Peripheral vascular disease, n (%)	1 (0.7)	1 (0.4)	0.112	0.749
Digestive diseases, $n$ (%)	9 (6.5)	11 (4.4)	0.772	0.380
SBP (mmHg)	$155.96 \pm 28.46$	$156.00 \pm 26.08$	0.014*	0.989
PR (beats/min)	$81.99 \pm 15.50$	$83.34 \pm 15.75$	0.814*	0.416
Medication in hospital				
ACEI, <i>n</i> (%)	118 (84.9)	210 (84.3)	0.021	0.885
ARB, <i>n</i> (%)	58 (41.7)	87 (34.9)	1.756	0.185
$\beta$ -blockers, $n$ (%)	133 (95.7)	236 (94.8)	0.157	0.692
CCB, <i>n</i> (%)	132 (95.7)	233 (93.6)	0.309	0.578
Diuretics, <i>n</i> (%)	54 (38.8)	93 (37.3)	0.085	0.770
Statins, $n$ (%)	73 (52.5)	54 (21.7)	38.511	< 0.001

\*t values. PR: Pulse rate; SBP: Systolic blood pressure; ACEI: Angiotensin-converting enzyme inhibitor; ARB: Angiotensin receptor blocker; CCB: Calcium channel blocker.

patients were not treated with aspirin ( $\chi^2 = 0.184$ , P = 0.668). The details are summarized in Table 2. Hemorrhage occurred in four patients, one (BARC Type 2) was in the aspirin group while the other three (1 BARC Type 2) and 2 BARC Type 5) were in the no-aspirin group. Recurrent dissection occurred in eight patients for endoleak, three of whom were in the aspirin group while five of them were in the no-aspirin group (2.3% vs. 2.2%, respectively,  $\chi^2 = 0.074$ , P = 0.785). Each group had one patient with myocardial infarction (0.8% and 0.4%, respectively,  $\chi^2 = 0.102$ , P = 0.749). No one had cerebral infarction in both groups. Overall, there was no significant difference in the end points between the two groups.

Eighteen patients were lost to follow-up at 12 months. Eighteen patients died during 12-month follow-up, of whom six (4.6%) patients were treated with aspirin and 12 (5.0%) patients were not treated with aspirin ( $\chi^2 = 0.027$ , P = 0.870). The details are summarized in Table 3. Hemorrhage occurred in nine patients, one (BARC Type 2) was in the aspirin group while the other eight patients (4 BARC Type 2 and 4 BARC Type 5) were in the no-aspirin group. Four patients had new dissection in the no-aspirin group at 12-month follow-up. The no-aspirin group had one patient with myocardial infarction at 12-month follow-up. No one had cerebral infarction in both groups. Overall, there was no significant difference in the end points between the two groups.

#### Clinical outcomes in antiplatelet subgroup

Of the patients who were treated with aspirin, 44 (31.7%) patients had taken dual-antiplatelet therapy (DAPT, aspirin + clopidogrel) and the other 95 (68.3%) patients had taken only aspirin. To evaluate the differences between DAPT and only aspirin, these 139 patients were divided into

# Table 2: Clinical outcomes at 1-month follow-upbetween the two groups

Aspirin group (n - 139)	No-aspirin group (n - 249)	χ²	Р
· · ·	. ,	0.005	0.944
1 (0.8)	1 (0.4)		0.749
0 (0.0)	2 (0.9)	0.102	0.749
5 (3.6)	7 (2.8)	0.184	0.668
1 (0.8)	3 (1.3)	0.005	0.944
2 (1.5)	2 (0.9)	0.005	0.944
2 (1.5)	2 (0.9)	0.005	0.944
3 (2.3)	5 (2.2)	0.074	0.785
3 (2.3)	5 (2.2)	0.074	0.785
1 (0.8)	1 (0.4)	0.102	0.749
0	0	_	-
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BARC: Bleeding Academic Research Consortium; -: Not applicable.

two groups, two and seven patients had lost to follow-up at 12 months in each group, respectively. The outcome comparison at 12 months between the two groups is shown in Table 4. Only one patient occurred hemorrhage in the only-aspirin group (0.0% vs. 1.1%,  $\chi^2 = 0.144$ , P = 0.704). Six patients died during 12-month follow-up, of whom 2 (4.8%) patients were treated with DAPT and four (4.5%) patients were in only-aspirin group ( $\chi^2 = 0.154$ , P = 0.695). Three patients had recurrent dissection for endoleak, all of whom were in the only-aspirin group ( $\chi^2 = 0.344$ , P = 0.558). Only one patient had myocardial infarction in the only-aspirin group compared to those in the DAPT group (2.4% vs. 0.0%, respectively,  $\chi^2 = 0.144$ , P = 0.704). There was no significant difference between the two groups at 12 months.

Table 3:	Clinical	outcomes	at	12-month	follow-up
between	the two	groups			

Items	Aspirin group ( <i>n</i> = 130)	No-aspirin group (n = 240)	χ²	Р
Hemorrhage, n (%)	1 (0.8)	8 (3.3)	1.381	0.240
BARC type 2	1 (0.8)	4 (1.7)	0.059	0.809
BARC type 5	0 (0.0)	4 (1.7)	0.909	0.340
Death	6 (4.6)	12 (5.0)	0.027	0.870
Cardiac death, $n$ (%)	1 (0.8)	4 (1.7)	0.059	0.808
Aortic death, $n$ (%)	2 (1.5)	5 (2.1)	0.001	0.974
Other causes of death, $n$ (%)	3 (2.3)	3 (1.3)	0.114	0.735
Endoleak, n (%)	3 (2.3)	5 (2.1)	0.054	0.816
Recurrent dissection, n (%)	3 (2.3)	9 (3.8)	0.194	0.660
Myocardial infarction, n (%)	1 (0.8)	2 (0.8)	0.293	0.588
Cerebral infarction	0	0	-	-

BARC: Bleeding Academic Research Consortium.

 Table 4: Clinical outcomes at 12-month follow-up

 between DAPT and the only-aspirin groups

		• .		
Items	DAPT ( <i>n</i> = 42)	Only aspirin $(n = 88)$	χ²	Р
Hemorrhage, n (%)	0 (0.0)	1 (1.1)	0.144	0.704
Death, $n$ (%)	2 (4.8)	4 (4.5)	0.154	0.695
Endoleak, n (%)	0 (0.0)	3 (3.4)	0.344	0.558
Recurrent dissection, n (%)	0 (0.0)	3 (3.4)	0.344	0.558
Myocardial infarction, n (%)	1 (2.4)	0 (0.0)	0.144	0.704
DADT. Dural anti-latelately				

DAPT: Dual-antiplatelet therapy.

# DISCUSSION

In this retrospective study, patients with TBAD and CHD who underwent EVAR shows favorable safety on antiplatelet therapy. In the absence of prospective, randomized trials, there were increasing evidences that EVAR shows a significant advantage over open surgery in patients with acute TBAD.<sup>[11-13]</sup> CHD had a high incidence in aortic disease patients.<sup>[14]</sup> Many studies had shown that CHD was the main cause of death after EVAR.<sup>[15,16]</sup> In addition, many studies had shown that patients with aortic disease combined with CHD should undergo PCI within 2 weeks after EVAR and should receive antiplatelet therapy.<sup>[5,8,10]</sup> In the present study, PCI was performed within 3–7 days after EVAR, and all the patients who were diagnosed to have CHD had received antiplatelet therapy.

Aortic dissection and CHD have common risk factors as follows: age, hypertension, and diabetes. The ACC/AHA guidelines for coronary angiography recommend coronary angiography before valve surgery or balloon valvotomy in an adult with chest discomfort or ischemia by noninvasive imaging, or in an adult free of chest pain but of substantial age and/or multiple risk factors for CHD.<sup>[17]</sup> In the present study, 139 (35.8%) patients had a coronary stenosis >50% and 44 (11.3%) patients had a coronary stenosis >70%. The 2014 ESC/EACTS Guidelines on myocardial revascularization suggest that PCI in CHD should be advised DAPT including

long-term oral aspirin followed by 75-100 mg daily plus clopidogrel 75 mg daily for 12 months.<sup>[14]</sup> However, there is no consensus on feasibility and safety on the use of antiplatelet therapy for patients with aortic dissection who underwent EVAR. In the present study, we evaluated the safety and necessary of antiplatelet therapy for TBAD treated with EVAR combined with CHD using end points such as hemorrhage, endoleak, recurrent dissection, death, myocardial infarction, and cerebral infarction. As our results showed that there is no significant difference at 1-month follow-up, the 12-month follow-up also showed no significant difference in all end points. The results indicated that long-term oral low-dose aspirin was safe for the TBAD patients who underwent EVAR. For the PCI subgroup, DAPT compared with only aspirin also showed no significance in hemorrhage, endoleak, recurrent dissection, death, and myocardial infarction. This was a single-center, retrospective study. The number of patients was not large and the follow-up was not long enough.

The present study indicated that long-term oral low-dose aspirin was safe for the patients with both TBAD and CHD who underwent EVAR. For patients who underwent both EVAR and PCI, DAPT also showed no increase in hemorrhage, endoleak, recurrent dissection, death, and myocardial infarction.

# **Financial support and sponsorship** Nil.

#### **Conflicts of interest**

There are no conflicts of interest.

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