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Optimal antiplatelet therapy after revascularization of left subclavian artery during TEVAR

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Abstract

Background Thoracic endovascular aortic repair (TEVAR) is a minimally invasive technique used to treat type B aortic dissections. Left subclavian artery (LSA) reconstruction is required when treating patients with involvement of LSA. The best antiplatelet therapy after LSA reconstruction is presently uncertain.

Methods This study retrospectively analyzed 245 type B aortic dissection patients who underwent left subclavian artery revascularization during TEVAR. Out of 245 patients, 159 (64.9%) were in the single antiplatelet therapy (SAPT) group, receiving only aspirin, and 86 (35.1%) were in the dual antiplatelet therapy (DAPT) group, receiving aspirin combined with clopidogrel. During the 6-month follow-up, primary endpoints included hemorrhagic events (general bleeding and hemorrhagic strokes), while secondary endpoints comprised ischemic events (left upper limb ischemia, ischemic stroke, and thrombotic events), as well as death and leakage events. Both univariate and multivariate Cox regression analyses were performed on hemorrhagic and ischemic events, with the Kaplan-Meier method used to generate the survival curve.

Results During the six-month follow-up, the incidence of hemorrhagic events in the DAPT group was higher (8.2% vs. 30.2%, $P < 0.001$). No significant differences were observed in ischemic events, death, or leakage events among the different antiplatelet treatment schemes. Multivariate Cox regression analysis showed that DAPT (HR: 2.22, 95% CI: 1.07–4.60, $P = 0.032$) and previous chronic conditions (HR:3.88, 95% CI: 1.24–12.14, $P = 0.020$) significantly affected the occurrence of hemorrhagic events. Chronic conditions in this study encompassed depression, vitiligo, and cholecystolithiasis. Carotid subclavian bypass (CSB) group (HR:0.29, 95% CI: 0.12–0.68, $P = 0.004$) and single-branched stent graft (SBSG) group (HR:0.26, 95% CI: 0.13–0.50, $P < 0.001$) had a lower rate of ischemic events than fenestration TEVAR (F-TEVAR). Survival analysis over 6 months revealed a lower risk of bleeding associated with SAPT during hemorrhagic events ($P = 0.043$).

Conclusions In type B aortic dissection patients undergoing LSA blood flow reconstruction after synchronous TEVAR, the bleeding risk significantly decreases with the SAPT regimen, and there is no apparent ischemic compensation

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within 6 months. Patients with previous chronic conditions have a higher risk of bleeding. The CSB group and SBSG group have less ischemic risk compared to F-TEVAR group.

Keywords TEVAR, Left subclavian artery revascularization, Antiplatelet, Aspirin, Clopidogrel, Aortic dissection

Introduction

Currently, TEVAR is widely acknowledged and has become the primary treatment for certain patients with thoracic descending aortic diseases [1, 2]. The European Society of Vascular Surgery and other guidelines recommend TEVAR as the primary treatment for descending thoracic aortic aneurysms (DTAA) [3–5]. Covering the left subclavian artery is advisable for patients lacking adequate proximal anchorage area. However, it increases the risks of stroke, spinal cord ischemia, and left upper limb ischemia [6]. In 2009, the Society of Vascular Surgery recommended routine revascularization when covering the left subclavian artery during TEVAR procedures [7]. Currently, clinical methods for LSA reconstruction, include carotid subclavian bypass (CSB), subclavian-carotid transposition (SCT) [8], fenestrated TEVAR(F-TEVAR) [9], single-branched stent graft(SBSG) [10], and other approaches. To mitigate adverse events of vascular embolism following left subclavian artery revascularization, practitioners often employ empirical antiplatelet therapy.

Aspirin is commonly employed in clinics to prevent cardiovascular and cerebrovascular events [11, 12], with its primary adverse reaction being bleeding [13, 14]. Dual antiplatelet therapy, combining aspirin and clopidogrel, is frequently utilized in secondary stroke prevention, reducing the risk of recurrent mild ischemic stroke and transient ischemic attack (TIA) [15, 16]. In their study assessing the safety and efficacy of antiplatelet therapy in patients with type B aortic dissection and coronary heart disease, He Ruixia found no significant difference in blood vessel patency between single antiplatelet therapy and dual antiplatelet therapies after endovascular abdominal aortic repair (EVAR). However, they observed an increased risk of bleeding with dual antiplatelet therapy, leading to their recommendation of long-term low-dose oral enteric aspirin. However it remains uncertain whether SAPT is superior to DAPT specifically for patients with type B aortic dissection [17]. Emma C Hansson and colleagues suggested that preoperative use of DAPT would elevate the risk of bleeding and blood transfusion, without impacting mortality. The study did not involve postoperative studies [18]. However, there are few reports on antiplatelet therapy after concomitant left subclavian artery revascularisation for TEVAR, the experience with SAPT does not directly extrapolate to this particular group of patients, and the optimal antiplatelet regimen remains unresolved.

Therefore, the objective of this study was to assess the efficacy and safety of both SAPT and DAPT regimens six months after simultaneous left subclavian artery revascularization for TEVAR. The aim is to provide clinicians with some insights to aid in selecting the most suitable antiplatelet regimen.

Subjects and methods

Study population

A retrospective analysis was conducted on patients who underwent TEVAR combined with left subclavian artery revascularization at Nanjing Drum Tower Hospital from January 2018 to May 2023. During the study of aspirin resistance, 441 patients were admitted to our center, and 245 type B aortic dissection patients were finally included in our study according to the standard of admission. Figure 1.

The inclusion criteria were as follows: (1) Patients undergoing TEVAR utilized F- TEVAR, SBSG and CSB for left subclavian artery reconstruction. They also received aspirin alone or in combination with clopidogrel after the operation. Exclusion criteria were: (1) patients diagnosed with stroke, coronary heart disease, myocardial infarction, hyperlipemia, hypertension combined with renal failure; (2) patients with a history of gastrointestinal bleeding or peptic ulcer disease; (3) patients with a history of major organ bleeding or severe bleeding disorders; (4) patients taking drugs that increase the risk of bleeding (such as non-steroidal anti-inflammatory drugs, corticosteroids, new oral anticoagulants and warfarin, etc.); (5) patients with severe heart, liver, and kidney dysfunction; (6) patients with coagulation disorders; (7) patients allergic to contrast agents; (8) any other condition that the researchers deemed unsuitable for inclusion in the study.

Research methods

Patients with type B aortic dissection were categorized based on the postoperative use of antiplatelet drugs into the SAPT group (159 cases) and the DAPT group (86 cases). The SAPT group received (100 mg/day) aspirin as monotherapy, whereas the DAPT group received a combination of (100 mg/day) aspirin and (75 mg/day clopidogrel) for six months. Clinical data were collected from patients, who were then followed up after discharge through a combination of in-person interviews and telephone calls. Blood pressure, clinical symptoms, and aorta CTA were documented. Chronic conditions in this study encompassed depression, vitiligo, and cholecystolithiasis.
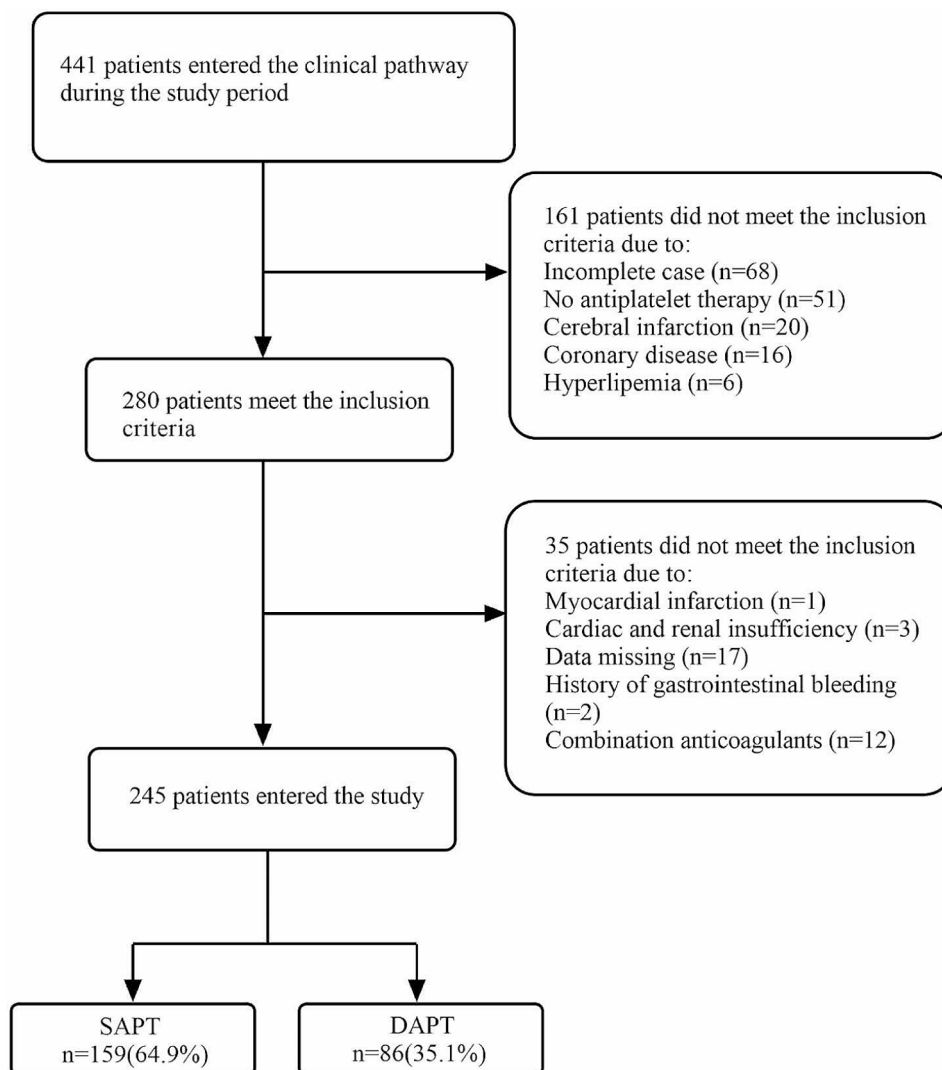
Fig. 1 Consort diagram of patient screening and allocation

Table 1 Bleeding grading standards of the Bleeding Academic Research Consortium [19]

Type	Clinical indications
1	Non-active bleeding, patients who do not need hospitalization; or patients who discontinue medication leading to bleeding
2	Any obvious active bleeding, meets one of the following conditions: requiring internal medical intervention, hospitalization, rapid assessment
3	Obvious bleeding with a decrease in hemoglobin of 3–5 g/dl; obvious bleeding requiring transfusion.
4	Not applicable
5	Fatal bleeding

General bleeding events include the upper digestive tract and eyes, etc., and the classification and definition standards are in accordance with the bleeding grading standards of the Bleeding Academic Research Consortium (BARC) [19]. Refer to Table 1 for more details.

Categorization of patients' surgical approaches based on LSA revascularization method: carotid-subclavian bypass (CSB), fenestrated TEVAR (F-TEVAR), and single-branched stent graft (SBSG).

The primary endpoint event is hemorrhagic events, classified according to the BARC classification. The secondary endpoints comprised death, leakage events and ischemic events (left upper limb ischemia, ischemic stroke, and thrombotic events). The thrombotic events encompassing the detection of stent filling defects, branching stents are not clear or in-stent thrombotic.

Statistical method

SPSS 26.0 statistical software and R version 4.3.0 software were used for data analysis. The measurement data were expressed as mean±standard deviation, and the count data were expressed as frequency and percentage. *T*-test was used for comparison and measurement data between

Table 2 Baseline characteristics, history, and laboratory tests between the two groups

Variable	Total (n=245)	Group		P
		SAPT (n=159)	DAPT (n=86)	
Age, (year)	55.2±12.9	55.2±13.5	55.2±12.0	0.999
Female, n (%)	37 (15.1)	25 (15.7)	12 (13.9)	0.712
Drinker, n (%)	58 (24.1)	35 (22.2)	23 (27.4)	0.379
Smoker, n (%)	88 (36.5)	56 (35.7)	32 (38.1)	0.709
Blood Transfusion Record, n (%)	8 (3.3)	5 (3.1)	3 (3.5)	1.000
Surgical History, n (%)	90 (36.9)	64 (40.5)	26 (30.2)	0.112
Previous Chronic Conditions, n (%)	16 (6.6)	11 (6.9)	5 (5.9)	0.755
Diabetes, n (%)	14 (5.7)	8 (5.0)	6 (6.9)	0.736
Hypertension, n (%)	185 (75.5)	118 (74.2)	67 (77.9)	0.521
Fenestrated TEVAR, n (%)	86(35.1)	46(28.9)	40(46.5)	0.006*
Single branched stent graft, n (%)	124(50.6)	84(52.8)	40(46.5)	0.345
Carotid subclavian bypass, n (%)	35(14.2)	29(18.2)	6(7.0)	0.016*
Lifetech Ankura™II	89 (36.3)	49 (30.8)	40 (46.5)	0.015*
GORE®	21 (8.6)	15 (9.4)	6 (6.9)	0.512
Mico Port Castor®	132(53.9)	92 (57.9)	40 (46.5)	0.089
COOK®	3 (1.2)	3 (1.9)	0 (0.0)	0.501
Diastolic Pressure, (mmHg)	82.3±15.9	82.7±15.2	81.5±17.1	0.570
Systolic Pressure, (mmHg)	143.9±25.5	144.2±24.8	143.3±27.0	0.807
BMI, (kg/m2)	25.5 (23.5–27.7)	25.3 (23.5–27.6)	25.7 (23.6–27.7)	0.570
Hospital Days, (day)	16.0 (12.0–21.0)	17.0 (12.0–22.0)	16.0 (13.0–19.0)	0.561
Operation Time, (min)	170.0 (120.0–290.0)	160.0 (120.0–292.5)	180.0 (131.2–275.0)	0.246
Platelet Count, (10^9/L)	188.1±66.7	187.2±67.9	189.8±64.8	0.779
Hemoglobin Count, (g/L)	135.0 (122.0–146.0)	134.0 (121.0–145.0)	137.0 (123.0–146.5)	0.363
PT, (s)	11.4 (10.9–12.1)	11.5 (11.0–12.1)	11.4 (10.9–12.0)	0.547
INR, (s)	1.00 (0.9–1.1)	1.00 (0.9–1.1)	1.00 (0.9–1.1)	0.698
APTT, (s)	27.1 (25.6–29.1)	27.4 (25.9–29.3)	26.8 (25.1–28.8)	0.100
TT, (s)	17.3 (16.5–18.2)	17.4 (16.7–18.3)	17.2 (16.3–18.0)	0.106
FBG, (g/L)	2.8 (2.3–4.0)	2.8 (2.3–4.0)	2.8 (2.4–4.1)	0.782
D-D, (mg/L)	3.3 (1.6–6.9)	3.3 (1.16–7.80)	3.2 (1.9–6.5)	0.761

BMI: Body Mass Index PT: Prothrombin time; INR: International normalized ratio; APTT: Activated partial thromboplastin time; TT: Thrombin time; FBG: Fibrinogen; D-D: D-dimer; min: minute; s: second. * Statistically significant values

Table 3 Clinical outcomes follow-up between the two groups

Variable	Total (n=245)	Group		P
		SAPT (n=159)	DAPT (n=86)	
Ischemic event, n (%)	59 (24.2)	38 (24.1)	21 (24.4)	0.949
Ischemic stroke, n (%)	3 (1.2)	3 (1.9)	0 (0.0)	0.498
Left arm ischemia, n (%)	17 (6.9)	10 (6.3)	7 (8.1)	0.596
Thromboembolic events, n (%)	41 (17.5)	27 (17.9)	14 (16.7)	0.814
Bleeding event, n (%)	39 (15.9)	13 (8.2)	26 (30.2)	<0.001*
BARC type1, n (%)	22 (9.1)	9 (5.7)	13 (15.5)	0.014*
BARC type2, n (%)	16 (6.6)	4 (2.5)	12 (14.3)	0.001*
BARC type3, n (%)	1 (0.4)	0 (0.0)	1 (1.2)	0.352
Death, n (%)	11 (4.5)	8 (5.1)	3 (3.5)	0.808
Cardiogenic death, n (%)	4 (1.6)	2 (1.3)	2 (2.3)	1.000
Aortic death, n (%)	5 (2.1)	1 (0.6)	1 (1.2)	1.000
Other causes of death, n (%)	2 (0.8)	5 (3.2)	0 (0.0)	1.000
Endoleak, n (%)	4 (1.7)	4 (2.6)	0 (0.0)	0.343

BARC: Bleeding Academic Research Consortium. *Statistically significant values

the two groups, the X^2 test was used for enumeration data, and the Fisher exact probability method was used for enumeration data with an expected frequency of less than 5. Univariate and multivariate Cox regression was used to analyze the influencing factors of bleeding events. Items with a $P<0.2$ were included in the multifactorial analysis. $P<0.05$ was considered statistically significant.

Result

Baseline information

The study included 245 type B aortic dissection patients, with 159 patients (64.9%) receiving aspirin monotherapy and 86 patients (35.1%) receiving aspirin in combination with clopidogrel dual antiplatelet therapy. The study comprised 86 cases of F-TEVAR, 124 cases of SBSG, and 35 cases of CSB. Significant differences were observed between the F-TEVAR group ($P=0.006$) and the CSB group ($P=0.016$) in the two baseline groups. The SAPT group used fewer Ankura™II ($P=0.015$) from Life tech. No significant differences were found in other baseline characteristics. As summarized in Table 2.

Clinical outcome

During the follow-up, one patient was lost to follow-up, and 11 patients died. Among them, 8 patients (5.1%) received aspirin treatment, while 3 patients (3.5%) received DAPT with aspirin and clopidogrel ($P=0.808$). Further details are summarized in Table 3. A total of 39 patients experienced hemorrhagic events, with 13 patients (9 BARC 1 type and 4 BARC 2 type) in the SAPT group, and 26 patients (13 BARC 1 type, 12 BARC 2 type, and 1 BARC 3 type) in the DAPT group, showing significant statistical difference ($P<0.001$). There were no significant differences observed in other endpoints.

Survival analysis of hemorrhagic and ischemic events

Survival analysis revealed a lower risk of bleeding associated with SAPT during hemorrhagic events ($P=0.043$). There was no significant difference in ischemic events between different antiplatelet regimens. Refer to Fig. 2 for a visualization of the data.

Cox regression analysis of influencing factors of bleeding and ischemic events

Utilizing binary Cox regression analysis to examine the influencing factors of hemorrhagic and ischemic events. Patient age, female, BMI, surgical type, DAPT, drinker, smoker, blood transfusion record, surgical history, diabetes, hypertension, and previous chronic conditions were included in the univariate regression model, with variables showing a significance of $P<0.2$ included in the
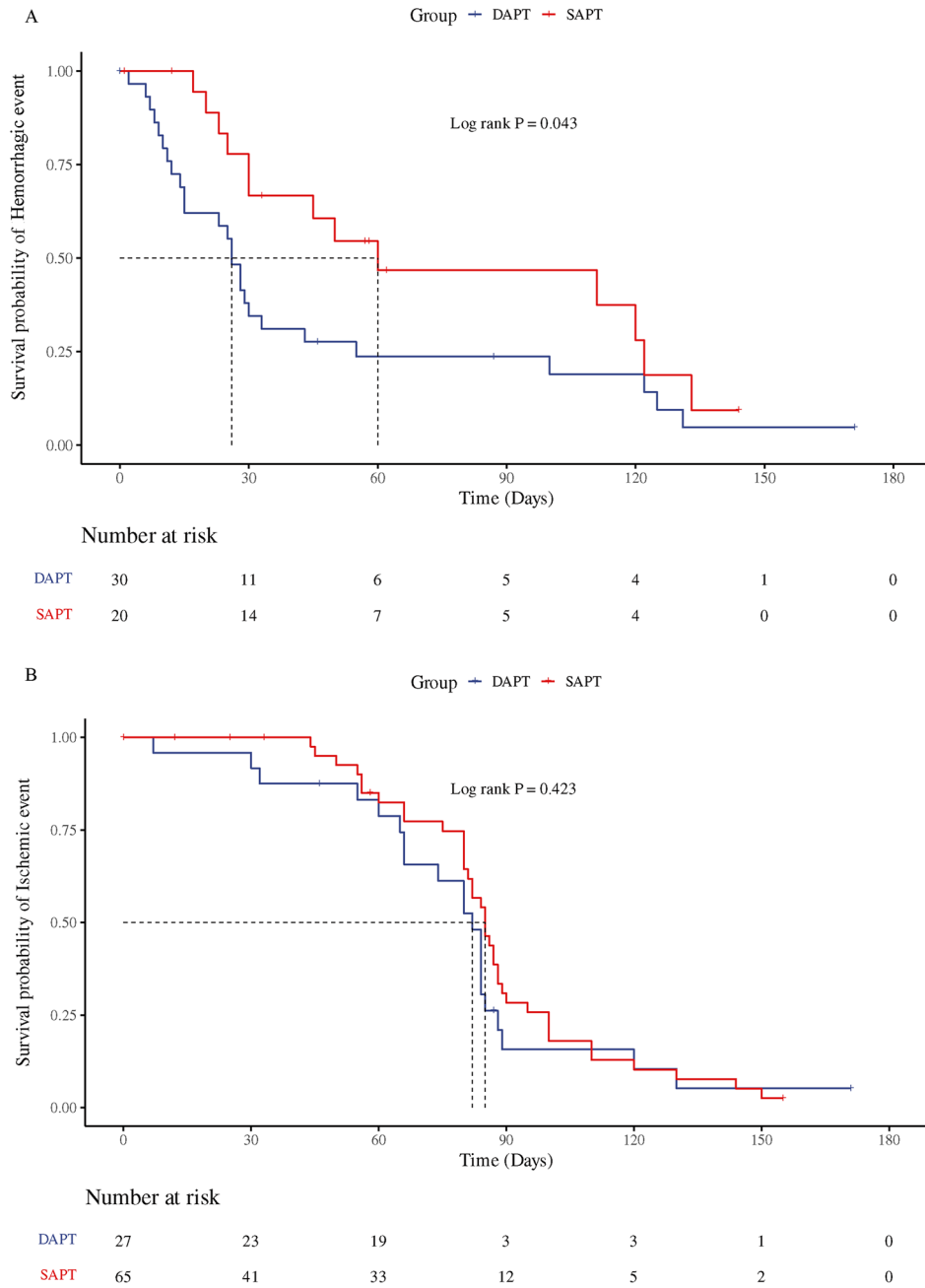
Fig. 2 Survival analysis of hemorrhagic and ischemic events. DAPT = dual-antiplatelet therapy. SAPT = single-antiplatelet therapy. (**A**) Analysis results of hemorrhagic event. (**B**) Analysis results of ischemic event
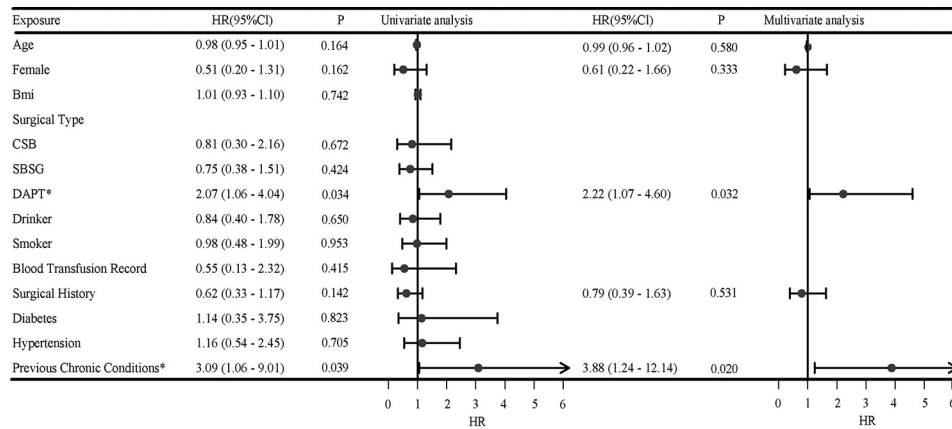
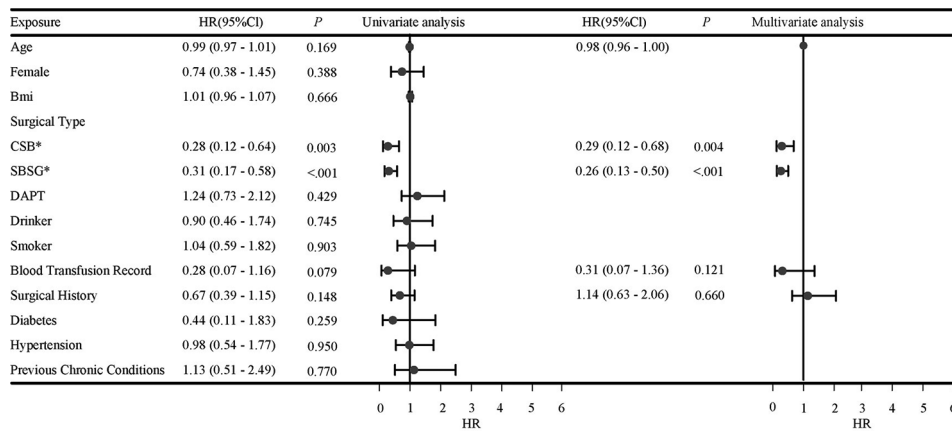**Fig. 3** Forest map of univariate and multivariate hemorrhagic events

Fig. 4 Forest map of univariate and multivariate ischemic events

multivariate analysis. In the univariate analysis of bleeding events, variables such as age, female, DAPT, surgical history, and previous chronic conditions are the criteria for inclusion in the multivariable analysis. Among them, DAPT (HR: 2.07, 95% CI: 1.06–4.04, *P*=0.034) and previous chronic conditions (HR: 3.09, 95% CI: 1.06–9.01, *P*=0.039) showed a significant difference. The results of a multivariate analysis indicate a significant increase in the risk of bleeding with DAPT (HR: 2.22, 95% CI: 1.07–4.60, *P*=0.032) and previous chronic conditions (HR: 3.88, 95% CI: 1.24–12.14, *P*=0.020). Further details are summarized in Fig. 3.

In the univariate analysis of ischemic events, variables such as age, CSB, SBSG, blood transfusion record and surgical history are the criteria for inclusion in the multivariable analysis. Among them, CSB (HR: 0.28, 95% CI: 0,12–0,64, *P*=0.003) and SBSG (HR: 0.31, 95% CI:0.17–0.58, *P*<0.001) showed a significant difference. The results of a multivariate analysis indicate a significant reduction in the risk of ischemic events with CSB (HR: 0.29, 95% CI: 0,12–0,68, *P*=0.004) and SBSG (HR: 0.26, 95% CI: 0,13–0,50, *P*<0.001) compared to F-TEVAR. Further details are summarized in Fig. 4.

Discussion

In type B aortic dissections, endovascular repair is commonly employed, for B dissections involving only the descending aorta, traditional straight tube stents are often used, with nearly 40% of cases involving the left subclavian artery. Reconstructing the left subclavian artery during TEVAR has gained wide recognition. Huang et al. [20], highlighted in a study evaluating the role of left subclavian artery revascularization in TEVAR that revascularization reduces the incidence of perioperative stroke and spinal cord ischemia (SCI), recommending its use in patients with LSA coverage during TEVAR. Leonhard-Bradshaw et al. [21], in their research assessing whether to reconstruct the left subclavian artery during TEVAR, they concluded that covering the LSA without revascularization increases the risk of stroke and SCI. Kimberly-Zamor et al. [22], proposed in a study comparing the incidence of LSA coverage during TEVAR and revascularization techniques that LSA coverage without

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revascularization during TEVAR increases the risk of stroke and upper limb ischemia. Methods of reconstructing the LSA artery during TEVAR include carotid subclavian bypass, fenestration stents, and castor-integrated single-branch stents [23]. However, due to narrow stent diameters and small artificial vessel calibers, stenosis and occlusion leading to ischemic events frequently occur.

The clinical application of antiplatelet therapy following LSA revascularization during TEVAR to prevent thromboembolic events originates from extensive research and understanding of antiplatelet inhibition in acute coronary syndrome and post-percutaneous coronary intervention (PCI) platelet activation [24]. Nevertheless, there are differences between TEVAR and PCI procedures. While antiplatelet therapy is generally administered post-LSA reconstruction, there is limited research on the use of antiplatelet therapy in patients undergoing left subclavian artery revascularization, with postoperative antiplatelet treatment strategies largely reliant on clinical judgment, lacking a consensus on their feasibility and safety.

To reduce the occurrence of ischemic events, antiplatelet therapy is often initiated postoperatively, albeit at the cost of increasing bleeding risk. Rational medication following LSA reconstruction can effectively improve patient prognosis. The occurrence of ischemic events such as stroke is one of the main risks after TEVAR surgery. Previous literature reports a lower incidence of stroke in patients undergoing LSA revascularization compared to those without LSA flow restoration [25]. However, there is currently a lack of research on the relationship between postoperative stroke occurrence in patients undergoing LSA reconstruction surgery and different antiplatelet treatment strategies. We found in this regression study that the risk of ischemic events was lower in CSB and SBSG reconstructive LSA approaches than in F-TEVAR, which is consistent with the results of a single-center study [23]. The use of DAPT was found to be ineffective in reducing ischemic events and increased the risk of bleeding within the 6-month study.

The majority of bleeding events in our study were non-disabling or non-fatal upper gastrointestinal bleeding, with fewer cases of severe bleeding such as hemorrhagic stroke, classified according to the US BARC classification. The results of the multivariate regression analysis showed that bleeding events in patients were not associated with increasing age, with dual antiplatelet therapy being the primary influencing factor to increase the risk of bleeding. Survival analysis results indicate that patients experience bleeding events mostly within 2 months, with an elevated risk of platelet bleeding associated with DAPT. Combining previous literature on post-percutaneous coronary intervention (PCI) [26] and post-peripheral arterial disease (PAD) studies [27], DAPT has been found to increase the risk of bleeding. The ideal clinical outcome is to reduce bleeding risk while preventing ischemic adverse events. In our study, the results were better with aspirin monotherapy, but in recent years, there have been more choices for monotherapy antiplatelet drugs, with clopidogrel monotherapy gradually replacing aspirin. In a study on post-PCI antiplatelet therapy, clopidogrel monotherapy was associated with a lower risk of bleeding compared to aspirin. Clopidogrel also showed greater advantages in balancing thrombosis formation and bleeding risk, but further substantial data is required for confirmation [28]. Our multivariate regression analysis results showed that a history of chronic diseases in patients increased the risk of ischemic events, necessitating further research and validation.

Our study results indicate that routine use of DAPT after LSA reconstruction does not provide additional benefits but increases the risk of bleeding. Therefore, our study supports that postoperative SAPT is a better therapeutic approach for patients. Patients with chronic diseases have a higher risk of ischemia. Decisions regarding antiplatelet drug use postoperatively should be made based on individual circumstances, with dynamic risk assessment of patients, weighing the cardiovascular event benefits against bleeding risks.

Limitation
The study has limitations. Due to the inclusion criteria, some patients with underlying diseases were excluded, and the results of the study could not be extended to these groups. The study is a single-center regression analysis. The study includes a relatively small number of patients, and the follow-up period is insufficient. Some patients may not adhere to the prescribed medication schedule and dosage. Subsequent research should consider enlarging the sample size to validate these findings.

Conclusion
In type B aortic dissection patients undergoing LSA blood flow reconstruction after synchronous TEVAR, the bleeding risk significantly decreases with the SAPT regimen, and there is no apparent ischemic compensation within 6 months. Patients with previous chronic conditions have a higher risk of bleeding. The CSB group and SBSG group have less ischemic risk compared to F-TEVAR group.

Abbreviations
TEVAR	Thoracic endovascular aortic repair
LSA	Left subclavian artery
SAPT	Single antiplatelet therapy
DAPT	Dual antiplatelet therapy
DTAA	Descending thoracic aortic aneurysms
SCT	Subclavian-carotid transposition
CSB	Carotid subclavian bypass
TIA	Transient ischemic attack
EVAR	Endovascular abdominal aortic repair
F-TEVAR	Fenestration TEVAR

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SBSG	Single-branched stent graft
BARC	Bleeding Academic Research Consortium
SCI	Spinal cord ischemia
PCI	Percutaneous coronary intervention
PAD	Post peripheral arterial disease

Declarations

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