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Dual antiplatelet therapy with aspirin and clopidogrel for type B aortic dissection patients: Cardiac and inflammatory benefits with bleeding risks

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Abstract: **Background**: In recent years, the incidence of type B aortic dissection (TBAD) has shown an upward trend. **Objective**: This study investigated the impact of dual antiplatelet therapy (DAPT) with aspirin and clopidogrel on TBAD, providing valuable insights for clinical management. **Methods**: A total of 120 TBAD patients admitted to our hospital between January 2022 and December 2023 were enrolled and randomized into two groups: A control group receiving standard treatment without DAPT and a research group receiving DAPT. Recovery time was measured in both groups. Cardiac function, coagulation parameters, inflammatory markers (interleukin [IL]-1β, IL-6, IL-10, tumor necrosis factor [TNF]-α, and systemic immune-inflammation index [SII]), and oxidative stress indicators (superoxide dismutase [SOD], glutathione peroxidase [GSH-Px], and malondialdehyde [MDA]) were assessed before and after treatment. Additionally, pain levels and adverse events, including bleeding and thrombotic risks, were monitored throughout the treatment period. **Results**: DAPT significantly shortens postoperative recovery time compared to aspirin monotherapy, highlighting its potential benefits in TBAD treatment. After treatment, analysis revealed more significantly improved cardiac and coagulation functions in the research group. Furthermore, compared with the control group, the research group had significantly lower levels of inflammatory factors and stress response and significantly higher levels of anti-inflammatory factors and antioxidant factors ($P<0.05$). During the short-term follow-up, the research group showed more pronounced pain relief and a reduced risk of thrombosis, albeit with an increased risk of bleeding. **Conclusion**: DAPT with aspirin and clopidogrel is more conducive to enhancing postoperative cardiac and coagulation functions and reducing inflammation in TBAD patients.

Keywords: Aspirin; Clopidogrel; Dual antiplatelet therapy; Type B aortic dissection

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INTRODUCTION

Type B aortic dissection (TBAD), which constitutes approximately 30-40% of all aortic dissection cases, primarily involves the descending aorta and spares the ascending aorta (Khaja & Williams, 2021). Although the acute mortality rate of TBAD is lower than that of type A aortic dissection (TAAD), its long-term prognosis remains concerning, with a 5-year survival rate of only 50-60% (Hameed *et al.*, 2023; Evangelista *et al.*, 2018). In recent years, the widespread adoption of thoracic endovascular aortic repair (TEVAR) has significantly improved the therapeutic outcomes of TBAD. Nevertheless, postoperative complications such as thrombosis and systemic inflammatory responses continue to pose significant clinical challenges (Yu *et al.*, 2023).

Antiplatelet therapy has been widely established as a cornerstone in the management of cardiovascular diseases. In particular, dual antiplatelet therapy (DAPT), which combines aspirin and clopidogrel, has demonstrated substantial clinical benefits and is widely endorsed (Sharma *et al.*, 2020; Howard & Khot, 2021). While studies on TAAD have shown that DAPT can enhance postoperative safety and improve patients' quality of life (Hansson *et al.*, 2019; Xiao *et al.*, 2022), its role in TBAD remains underexplored. TBAD patients often exhibit coagulation abnormalities and heightened inflammatory responses after surgery, which may be attributed to vascular endothelial injury, platelet activation and the release of systemic inflammatory mediators (Schizas *et al.*, 2023). Thus, investigating the impact of DAPT on coagulation function and systemic inflammation following TBAD surgery holds crucial clinical implications. This study systematically evaluated the comprehensive effect of DAPT in TBAD patients after TEVAR, focusing on the patients' cardiac function, coagulation, inflammation, oxidative stress, pain and prognosis. The direct comparison with single drug therapy can effectively make up for the research gap or controversy of antiplatelet therapy in the field of TBAD and provide innovative ideas for optimizing the comprehensive management strategy of TBAD.

MATERIALS AND METHODS

Study design

A prospective randomized controlled trial was conducted, enrolling patients diagnosed with TBAD at our hospital between January 2022 and December 2023. The sample size was determined using G*Power software. The expected effect size of the primary outcome (change in D-

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D) was set as 0.5, the significance level α=0.05 (two-sided) and the power 1-β=0.80. It was calculated that a minimum of 47 patients per group would be required. To allow for possible loss to follow-up and dropout (10% possible), after applying the predefined inclusion and exclusion criteria, a total of 120 TBAD patients were recruited for the study.

Inclusion criteria

(1) Age ≥ 18 years; (2) Radiologically confirmed diagnosis of TBAD (Stanford type B or DeBakey type III); (3) Symptom onset within 14 d prior to enrollment; (4) Scheduled to undergo TEVAR at our hospital.

Exclusion criteria

(1) Concurrent diagnosis of TAAD or other severe cardiovascular comorbidities; (2) Presence of active infections, malignancies, or autoimmune disorders; (3) Severe hepatic or renal dysfunction (Child-Pugh class C or estimated glomerular filtration rate [eGFR]<30 mL/min/1.73 m^2); (4) History of hypersensitivity or contraindications to study medications; (5) Bleeding diathesis or recent hemorrhagic events; (6) Long-term use of anticoagulant or antiplatelet agents; (7) Pregnant or lactating females; (8) Inability to complete follow-up assessments; (9) Death during the follow-up period. Eligible patients were randomly assigned in a 1:1 ratio to either the control group without DAPT (n=60) or the research group with DAPT (n=60) with the use of a computer-generated random number sequence, with assignment concealed by sealed opaque envelopes. All the study subjects and sample collectors and testers were unaware of the grouping.

Surgical procedure

All TEVAR surgeries were performed by the same surgical team in our hospital and rehabilitation nursing for TEVAR was received after surgery. Under general anesthesia, the femoral artery was accessed via percutaneous puncture, followed by standard vascular angiography. A guidewire was advanced through the femoral artery to the targeted aortic lesion site. Under X-ray fluoroscopy, the stent graft was precisely positioned and deployed to cover the affected aortic segment, with adjunctive balloon angioplasty performed if necessary to ensure optimal stent expansion. Contrast agent was subsequently reinjected to confirm accurate stent placement. The catheter and guidewire were then carefully withdrawn and the femoral artery access site was managed either by manual compression or surgical closure. Postoperatively, patients were monitored intensively for 24 h. Renal function was closely monitored through urine output and serial serum creatinine measurements to mitigate the risk of contrast-induced nephropathy.

Nursing procedure

(1) Routine continuous vital signs and hemodynamic monitoring were performed within 1 day after operation. Patients were kept in the supine position or lateral position before awakening from anesthesia and were helped to turn over every 2 hours. (2) Two to four d after surgery, the patient's condition was monitored continuously and the cough was encouraged and a scientific progressive rehabilitation exercise plan was established, starting from simple bed exercise according to the patient's body tolerance. (3) 5 to 7 d after operation. The patients were instructed to sit up at the bedside. At first, the patients were kept in the sitting position for 1-5 min and the sitting time was gradually extended according to the patient's body recovery. For patients with good rehabilitation, they can be appropriately guided to complete the bedside standing exercise and the standing time can also be gradually extended. (4) 8 to 14 d after operation. During this period, positive language was used to establish a positive thinking style for patients and healthy lifestyle and precautions were taught after discharge. (5) Discharge guidance was provided to the family members of patients, explaining the nursing needs, nursing skills, possible adverse reactions during home and coping styles of patients after discharge and informing the family members of patients to maintain an encouraging and approving attitude towards patients in daily life and assist them to complete various life activities as much as possible.

Medication regimen

Control group: 24 hours postoperatively, patients were prescribed aspirin (Jilin Jinheng Pharmaceutical Co., Ltd., H22023296) at a standard dose of 100 mg once daily. Research group: In addition to aspirin (administered as in the control group), patients in this group received clopidogrel (Lepu Pharmaceutical Co., Ltd., H20123116) at a dose of 75 mg once daily. Both groups adhered to their respective treatment protocols for 6 months.

Sample collection and testing

Cardiac function parameters: left ventricular ejection fraction (LVEF) and left ventricular end-diastolic dimension/volume (LVEDD/LVEDV), were evaluated using a standardized cardiac function analyzer before and after treatment. In addition, fasting venous blood samples were collected and divided into three aliquots for comprehensive laboratory analyses: One aliquot was utilized for the detection of activated partial thromboplastin time (APTT), prothrombin time (PT), thrombin time (TT), fibrinogen (FIB) and D-dimer (D-D) using a coagulation function analyzer. Another aliquot was applied to measure interleukin-1β/6/10 (IL-1β/6/10), tumor necrosis factor-α (TNF-α), superoxide dismutase (SOD), malondialdehyde (MDA) and glutathione peroxidase (GSH-Px) via enzyme-linked immunosorbent assay (ELISA) kits. The final aliquot was used to determine platelet count (PLT), lymphocyte count (LYM) and neutrophil-to-lymphocyte ratio (NLR) with an automated hematology analyzer and the systemic immune-inflammation index (SII) was calculated (PLT × NLR / LYM).

Prognostic follow-up

Upon discharge, patients were subjected to a six-month follow-up to monitor clinical outcomes. Follow-up assessments were conducted at monthly intervals and included the following evaluations: (1) Pain intensity was assessed using the Visual Analogue Scale (VAS) (Astrom *et al.*, 2023) at baseline (T0) and 2 months (T1), 4 months (T2) and 6 months (T3) post-treatment. (2) Any risk events during the treatment course, including thrombosis, bleeding, delirium, among others, were recorded.

Statistical analysis

All statistical analyses were performed in SPSS 26.0 (IBM Corp.). Categorical variables [n (%)] underwent χ^2 testing. Continuous variables (The distribution of the data was confirmed using the Shapiro-Wilk test) with normal distribution [$\bar{\chi}\pm s$] were evaluated using independent t-tests (comparison between groups), paired t test (within group comparison), while non-parametric alternatives [Mann-Whitney U (comparison between groups) and Wilcoxon tests (within group comparison)] addressed non-normally distributed data [M(P25, P75)]. All statistical tests were two-sided with a significance level of $\alpha=0.05$. $P<0.05$ was considered statistically significant.

RESULTS

Comparison of baseline clinical characteristics

Baseline clinical characteristics were compared between the control group and the research group and none of the differences between the two groups were statistically significant ($P>0.05$) (Table 1).

Comparison of recovery status

Perioperative analysis revealed comparable hospitalization durations between groups ($P>0.05$), while the research group achieved superior respiratory recovery with shorter endotracheal intubation periods and earlier ambulation initiation ($P<0.05$) (Table 2).

Comparison of cardiac function

Cardiac function improvements were observed in both cohorts, with post-treatment LVEF elevation and reductions in LVEDD/LVEDV ($P<0.05$). Although ventricular dimension parameters showed intergroup equivalence, the research group maintained a significant LVEF advantage ($P<0.05$) (Fig. 1).

Comparison of coagulation function

Both groups exhibited a significant reduction in FIB and D-D levels following the treatment ($P<0.05$). Intergroup comparisons revealed no significant differences in PT, APTT, TT, or FIB ($P>0.05$), but the research group demonstrated significantly lower D-D levels compared to the control group ($P<0.05$) (Fig. 2).

Comparison of inflammatory responses

Inflammatory modulation analysis showed baseline cytokine parity ($P>0.05$). Post-intervention, both groups displayed attenuated pro-inflammatory markers. Notably, the research group outperformed controls in IL-1β suppression, SII reduction and IL-10 elevation ($P<0.05$) (Fig. 3).

Comparison of oxidative stress markers

Post-treatment analysis revealed significant improvements in oxidative stress markers across both cohorts ($P<0.05$), manifested through elevated SOD/GSH-Px and reduced MDA levels. However, the research group demonstrated more pronounced antioxidant effects ($P<0.05$) (Fig. 4).

Comparison of prognostic outcomes and pain assessment

Comparative results demonstrated clinical benefits in the research group with (1) lower mean VAS scores at T1-T2 and (2) a reduced risk of stent thrombosis but increased bleeding events compared with the control group ($P<0.05$) (Table 3).

DISCUSSION

In this investigation, we examined the impact of DAPT on TBAD and discovered that DAPT surpassed antiplatelet monotherapy in enhancing postoperative cardiac performance, improving coagulation parameters and alleviating inflammatory responses in patients, suggesting that DAPT stands as a superior therapeutic regimen for TBAD. Aspirin combined with clopidogrel was selected as the DAPT regimen in this study, mainly based on the following considerations: (1) Clopidogrel has a long history of use in the secondary prevention of cardiovascular diseases and its efficacy and safety data are sufficient; (2) Compared with newer P2Y12 inhibitors such as ticagrelor, clopidogrel was less costly and more readily available and widely used in clinical practice at the time (when the study was designed) and in the region; (3) The study was designed to evaluate the efficacy of DAPT regimens commonly used in clinical practice in patients with TBAD.

Delving deeper into the postoperative recovery metrics, the research group receiving DAPT demonstrated markedly superior outcomes compared to the control group, particularly in terms of reduced endotracheal intubation and expedited mobilization ($P<0.05$). Varma PK *et al*. also reported that DAPT was more conducive to reducing the duration of endotracheal intubation (Varma *et al.*, 2021), consistent with our findings. The mechanism is that DAPT exerts a more pronounced suppression on platelet activation and aggregation, mitigates post-stent thrombosis, and ensures stent patency (Dobesh *et al.*, 2020) and diminishes myocardial ischemia risk, thereby facilitating a swifter postoperative functional recovery. Additionally, comparative analysis of cardiac function pre- and post-treatment revealed that the DAPT group exhibited a lower LVEF level ($P<0.05$), underscoring DAPT's enhanced efficacy in ameliorating cardiac function.

Table 1: Clinical data

Projects	Control (n=60)	Research (n=60)	t, χ^2	P
Age	55.08±8.51	57.60±6.94	1.78	0.08
Male	47 (78.33%)	51 (85.00%)	0.89	0.35
Hypertension	43 (71.67%)	46 (76.67%)	0.39	0.53
Diabetes mellitus	25 (41.67%)	27 (45.00%)	0.14	0.71
Smoking	34 (56.67%)	29 (48.33%)	0.84	0.36
Extracorporeal circulation time (min)	156.35±18.68	157.18±16.37	0.26	0.80
Aortic block time (min)	80.22±12.49	81.57±9.54	0.67	0.51
Operation time (h)	5.52±0.79	5.62±0.69	0.74	0.46

Table 2: Recovery status

Projects	Control (n=60)	Research (n=60)	t	P
Duration of endotracheal intubation (h)	4.02±1.44	3.42±1.29	2.40	0.02
ICU stay (d)	1.68±0.68	1.53±0.62	1.26	0.21
Time to postoperative ambulation (d)	3.00±1.34	2.53±1.02	2.15	0.03
Hospital stays (d)	6.57±1.50	6.78±1.22	0.88	0.39

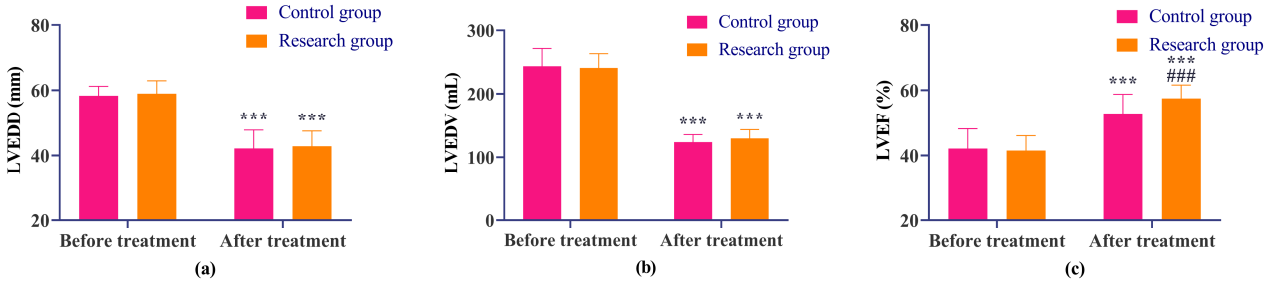

Fig. 1: Cardiac function.
(a) Comparison of LVEDD before and after treatment in the two groups, (b) Comparison of LVEDV before and after treatment in the two groups, (c) Comparison of LEVF before and after treatment in the two groups. *** denotes P<0.001 compared to before treatment and #### denotes P<0.001 compared to the control group.

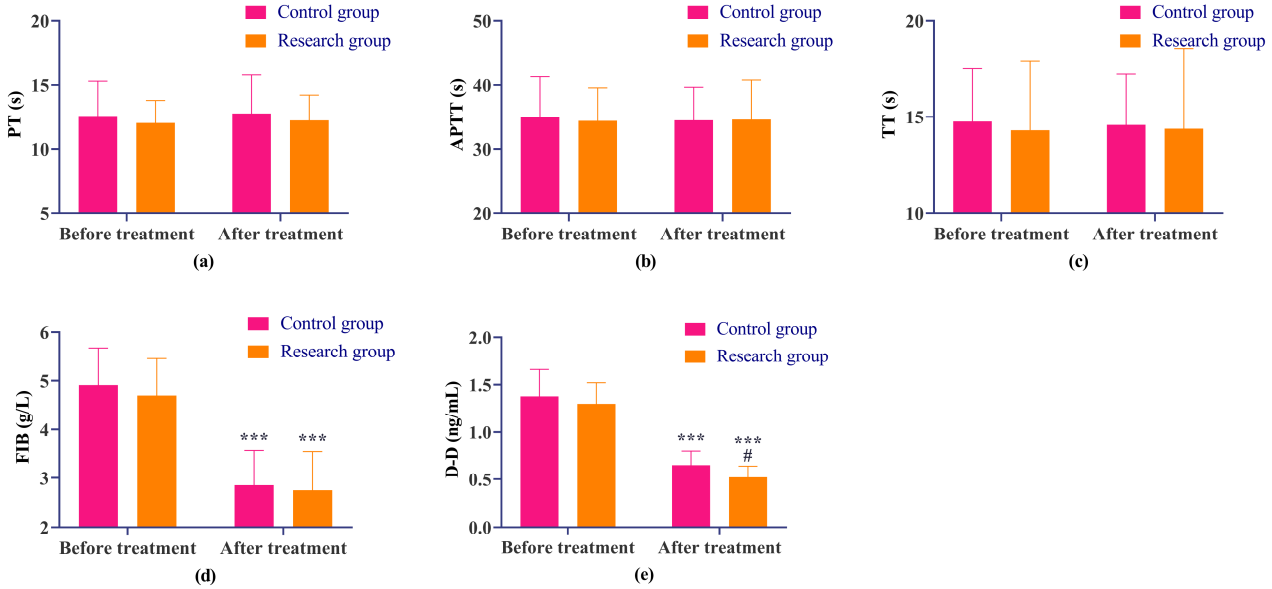

Fig. 2: Coagulation function.
(a) Comparison of PT before and after treatment in the two groups, (b) Comparison of APTT before and after treatment in the two groups, (c) Comparison of TT before and after treatment in the two groups, (d) Comparison of FIB before and after treatment in the two groups, (e) Comparison of D-D before and after treatment in the two groups. *** denotes P<0.001 compared to before treatment and #### denotes P<0.001 compared to the control group.

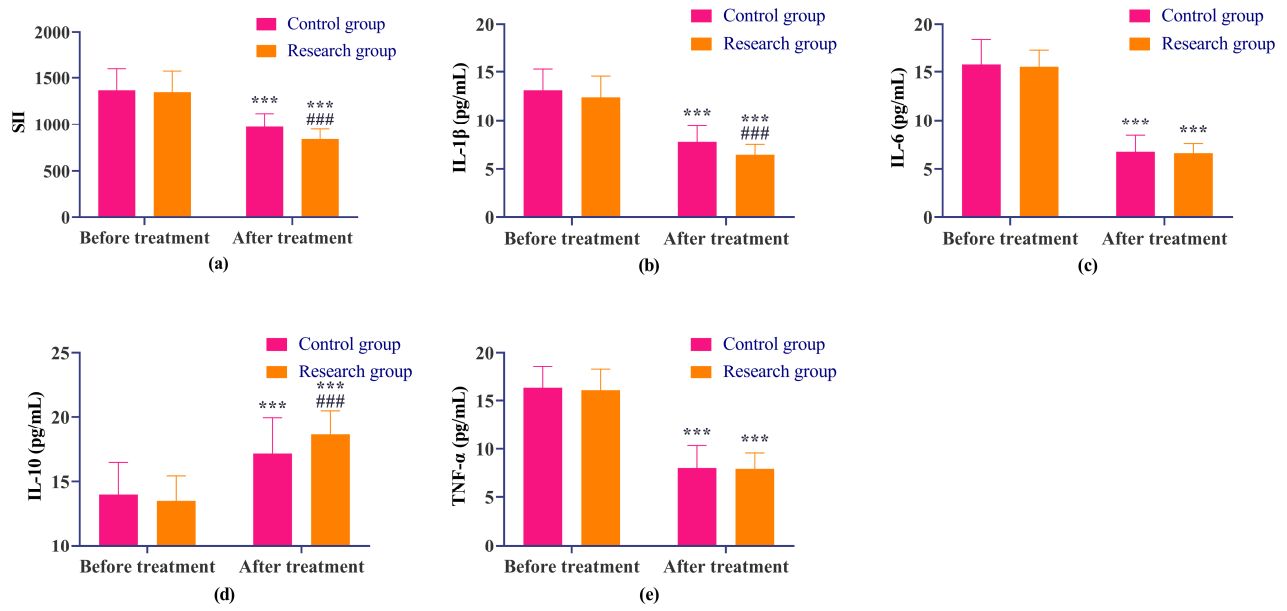

Fig. 3: Inflammatory responses.
(a) Comparison of SII before and after treatment in the two groups, (b) Comparison of IL-1β before and after treatment in the two groups, (c) Comparison of IL-6 before and after treatment in the two groups, (d) Comparison of IL-10 before and after treatment in the two groups, (e) Comparison of TNF-α before and after treatment in the two groups. *** denotes P<0.001 compared to before treatment and #### denotes P<0.001 compared to the control group.

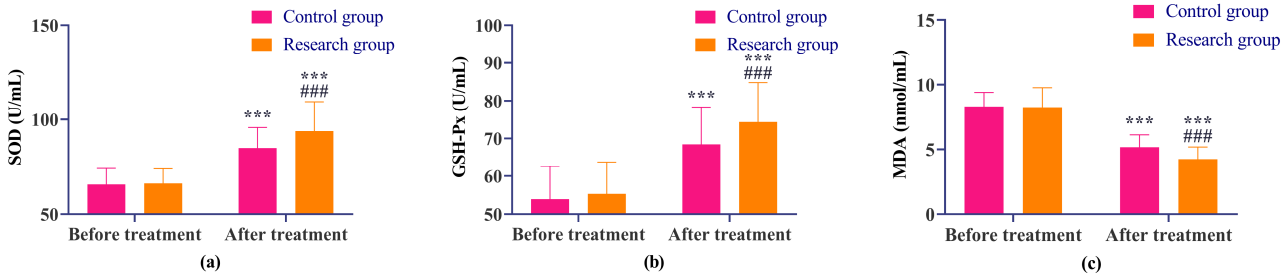

Fig. 4: Oxidative stress markers.
(a) Comparison of SOD before and after treatment in the two groups, (b) Comparison of GSH-Px before and after treatment in the two groups, (c) Comparison of MDA before and after treatment in the two groups. *** denotes P<0.001 compared to before treatment, # denotes P<0.05 compared to control group. *** denotes P<0.001 compared to before treatment and #### denotes P<0.001 compared to the control group.

Table 3: Prognostic outcomes and pain assessment

Projects		Control (n=60)	Research (n=60)	t, χ^2	P
VAS	T0	7.27±1.30	7.23±1.25	0.14	0.89
	T1	4.85±1.48	4.27±1.25	2.33	0.02
	T2	2.73±0.80	2.10±0.73	4.53	<0.001
	T3	1.33±0.51	1.22±0.52	1.24	0.22
Adverse reaction	Bleeding	4 (6.67%)	12 (20.00%)	4.62	0.03
	Lung infection	2 (3.33%)	1 (1.67%)	0.34	0.56
	In-stent thrombosis	7 (11.67%)	1 (1.67%)	4.82	0.03
	Pericardial tamponade	3 (5.00%)	4 (6.67%)	0.16	0.70
	Kidney Injury	0 (0.00%)	1 (1.67%)	1.01	0.32
	Secondary surgery	1 (1.67%)	1 (1.67%)	1.00	1.00
	Cerebrovascular accident	7 (11.67%)	6 (10.00%)	0.09	0.77

Nonetheless, it is imperative to acknowledge DAPT's principal limitation: an elevated propensity for hemorrhagic complications in patients. In numerous prior investigations into DAPT, hemorrhagic adverse events have been consistently highlighted (Mangieri *et al.*, 2020; Valgimigli *et al.*, 2024), a perspective that is substantiated by the prognostic outcomes delineated in this study. The occurrence of bleeding events disrupts the hemodynamic equilibrium of patients, thereby imposing an augmented burden on the heart and, paradoxically, hindering the recuperation of cardiac functionality. Our findings reveal that, despite a higher incidence of bleeding events in the DAPT cohort compared to the control group, the former exhibited superior cardiac performance. This implies that, with stringent management of postoperative bleeding risks, the administration of DAPT is more beneficial for patient recovery.

Furthermore, to comprehensively assess the impact of DAPT on TBAD, we conducted an in-depth analysis across three critical dimensions: coagulation function, inflammation and oxidative stress. The results demonstrated improvements in these parameters across both cohorts after treatment, with the DAPT group exhibiting more pronounced enhancements. This evidence suggests that DAPT not only facilitates the amelioration of coagulation dynamics but also significantly attenuates inflammatory and oxidative stress responses in TBAD patients. Extensive prior research has established that antiplatelet therapy generally exerts no significant influence on patients' PT, APTT, or TT (Bonetti *et al.*, 2023). In contrast, alterations in FIB levels are predominantly linked to preoperative inflammatory responses, oxidative stress, surgical consumption and hemodilution (Sulimai & Lominadze, 2020).

With respect to D-D, the preoperative occurrence of AD induces intimal tearing, which activates both the coagulation and fibrinolytic systems, leading to markedly elevated D-D levels (Sakamoto *et al.*, 2023). Following the administration of DAPT, the suppression of thrombus formation indirectly contributes to a reduction in D-D levels. However, this notable decline in D-D is concomitant with an elevated risk of hemorrhage, thereby reinforcing the imperative for vigilant monitoring of bleeding risks in the clinical deployment of DAPT. In anti-inflammatory research on DAPT, clinical evidence has demonstrated that the synergistic use of aspirin and clopidogrel inhibits platelet activation through multiple mechanisms, curtailing the release of inflammatory mediators, particularly by attenuating platelet-leukocyte interactions (Dong *et al.*, 2022). Moreover, DAPT mitigates the generation of free radicals mediated by platelet activation, thereby ameliorating oxidative stress responses (Diana *et al.*, 2024). These findings are congruent with the results reported by Jastrzebska M and Zhou T *et al*. (Jastrzebska *et al.*, 2018; Zhou *et al.*, 2021), thereby substantiating our conclusions.

Comparative analysis revealed two key findings: First, the intervention group demonstrated the anticipated reduction in thrombosis risk relative to controls. Second and more notably, significantly lower pain levels were observed in the intervention cohort at both T1 and T2 timepoints compared to the control group. For ischemic pain, DAPT more effectively alleviates tissue ischemia-induced pain by mitigating thrombus formation; regarding inflammatory pain, DAPT's superior anti-inflammatory properties contribute to enhanced suppression of inflammatory pain; however, DAPT does not exert a direct influence on vasodilatory pain resulting from mechanical injury and stretching of the vascular wall. As a result, the research group demonstrated more significant pain relief in the short term. DAPT was also shown to be more effective in improving pain in patients in a study of acute coronary syndromes (Zhou *et al.*, 2023). However, it must be noted that the risk of bleeding was significantly higher in the research group than in the control group. Therefore, the implementation of DAPT in the future must be accompanied by a strict strategy for the management of bleeding risk. We suggest that when prescribing DAPT for patients with TBAD (especially after TEVAR), clinicians need to strictly evaluate the baseline bleeding risk of patients and optimize the DAPT duration to balance the benefits (such as thromboprophylaxis) and risks (bleeding). Future studies need to explore the optimal DAPT duration for patients with TBAD. At the same time, it is also important to strengthen patient education, recognize the symptoms of bleeding and seek medical treatment in time. Patients need to be closely monitored, regularly followed up and pay attention to hemoglobin, fecal occult blood and other indicators and be alert for any signs of bleeding. For patients at high bleeding risk, consider alternatives (e.g., monotherapy) or gastrointestinal protection with proton-pump inhibitors.

Nevertheless, this study has limitations. This study was a single-center study with relatively single patient source and workflow, so extrapolation of the results may be limited. There may be differences in surgical techniques, baseline characteristics of patients and postoperative management strategies among different centers, which may affect the generalizability of DAPT. The relatively short follow-up period precludes the evaluation of long-term patient outcomes. Furthermore, additional clinical indicators are required to comprehensively assess the impact of DAPT on TBAD. Additionally, potential variations in the efficacy of aspirin and clopidogrel manufactured by different producers cannot be excluded. Therefore, a meta-analysis incorporating a larger dataset is warranted. Future multi-center, large-sample studies are needed to verify our findings.

CONCLUSION

The DAPT regimen combining aspirin and clopidogrel effectively attenuates postoperative inflammatory

responses and oxidative stress, enhances cardiac function, reduces thrombotic risk and promotes recovery in patients with TBAD. However, the use of DAPT is associated with an increased risk of bleeding, necessitating rigorous monitoring of patients' bleeding risk in clinical practice to optimize the therapeutic benefits of DAPT.

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Authors' contributions
Ping Feng conceived and designed the study, Hao Zhang wrote and revised the manuscript, Pingfeng and Hao Zhang collected and analyzed data. All authors read and approved the final submitted manuscript.

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Data availability statement
The data used to support the findings of this study are available from the corresponding author upon request.

Ethical approval
The study involving human subjects complied with the Declaration of Helsinki and was approved by the ethical committee of the Nanjing First Hospital, Nanjing Medical University (No. KY20220518-01-KS-01) and all participants provided written informed consent.

Conflict of interest
The authors declare that they have no competing interests.

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