Comparison of mid-term outcomes of endovascular repair and medical management in patients with acute uncomplicated type B aortic dissection

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ABSTRACT

Objectives: To further assess the early and mid-term outcomes of thoracic endovascular aortic repair (TEVAR) in patients with acute uncomplicated type B aortic dissection (TBAD) compared with those receiving best medical treatment (BMT).

Methods: Between February 2008 and March 2018, 357 consecutive patients with acute uncomplicated TBAD were retrospectively analyzed. Among them, 191 patients underwent TEVAR, and 166 received BMT. After propensity score matching, we obtained 145 matched pairs for analysis.

Results: In the matched population, the 30-day mortality between the TEVAR group and the BMT group showed no statistically significant difference, whereas the early adverse events rates in the TEVAR group were significantly greater than that of the BMT group ($P = .003$). Freedom from all-cause mortality in the TEVAR group was significantly greater than that of the BMT group (TEVAR: 91.9% at 5 years, BMT: 82.2% at 5 years, $P = .028$). Freedom from aortic-related mortality in the TEVAR group was significantly greater than that of the BMT group (TEVAR: 94.1% at 5 years, BMT: 86.1% at 5 years, $P = .044$). Multivariable Cox-hazard regression analysis demonstrated that the older age (hazard ratio [HR], 1.04; 95% confidence interval [CI], 1.01-1.08, $P = .013$), BMT (HR, 2.33; 95% CI, 1.08-5.05, $P = .032$), and the distance between the primary entry tear and the left subclavian artery <2.0 cm (HR, 2.30; 95% CI, 1.06-4.99, $P = .035$) were the significant risk factors for all-cause death. Given death as a competing factor, the cumulative incidence of rupture in the BMT group was significantly greater than that of the TEVAR group (BMT: 13.7% at 5 years, TEVAR: 5.1% at 5 years, $P = .024$).

Conclusions: Despite more complications in the early stage, TEVAR was associated with decreased risk of late death and had fewer late aortic ruptures compared with BMT in patients with acute uncomplicated TBAD. Therefore, TEVAR may be considered as the first option to improve the late outcomes in these patients. (*J Thorac Cardiovasc Surg* 2021;162:26-36)

Freedom from all-cause death between the TEVAR and BMT groups.

CENTRAL MESSAGE

TEVAR was associated with a better mid-term survival and fewer late aortic ruptures compared with BMT in patients with acute uncomplicated TBAD. TEVAR may be considered the first option.

PERSPECTIVE

This large-sample retrospective study suggested that TEVAR was associated with a lower rate of late aortic ruptures and late mortality compared with BMT in patients with acute uncomplicated TBAD. Randomized controlled trials are needed to compare the mid- and long-term outcomes of TEVAR with BMT in these patients.

See Commentaries on pages 37 and 38.

Acute type B aortic dissection (TBAD) is a life-threatening condition with characteristics of sudden onset, rapid progression, and high mortality.^{1,2} Benefiting from the lower

perioperative mortality than open surgery, thoracic endovascular aortic repair (TEVAR) has become the treatment of choice for acute complicated TBAD.^{3,4} Traditionally,

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Abbreviations and Acronyms

A-AD	= type A aortic dissection
BMT	= best medical treatment
CI	= confidence interval
CTA	= computed tomography angiography
HR	= hazard ratio
LCCA	= left common carotid artery
LSA	= left subclavian artery
PSM	= propensity score matching
SBP	= systolic blood pressure
TBAD	= type B aortic dissection
TEVAR	= thoracic endovascular aortic repair

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patients with uncomplicated TBAD are treated conservatively by controlling hypertension and close monitoring; in other words, the best medical treatment (BMT).⁵ However, the long-term outcomes of BMT in patients with uncomplicated TBAD are less than satisfactory, with a reported 30% to 50% cumulative mortality at 5 years and a 20% to 50% delayed false-lumen expansion at 4 years.⁶⁻⁸

TEVAR has the advantage of stabilizing a dissected aorta, inducing aortic remodeling processes, and promoting false lumen thrombosis.⁴ A thrombosed false lumen is associated with improved survival and reduced late adverse events of acute TBAD.⁹ Given this fact, preemptive TEVAR has also been performed in patients with acute uncomplicated TBAD to reduce late morbidity and mortality.⁹⁻¹² Recently, a few published studies have compared the early and late outcomes of TEVAR with BMT in patients with acute uncomplicated TBAD.⁹⁻¹³ However, the majority of these studies have been based on limited numbers of patients and/or short follow-up period^{10,14-17} and did not reach consistent conclusions regarding the early and late outcomes of TEVAR in patients with acute uncomplicated TBAD. The purpose of this retrospective study was to further assess the early and mid-term outcomes of TEVAR in patients with acute uncomplicated TBAD compared with those receiving BMT.

PATIENTS AND METHODS

Study Population

Between February 2008 and March 2018, all patients with acute uncomplicated TBAD were retrospectively obtained from medical records of the Union Hospital of Huazhong University of Science and Technology. Aortic dissection was classified as type B following the Stanford classification.

Acute aortic dissection was considered if patients received treatment within 14 days of initial symptom onset. Acute uncomplicated TBAD is defined as dissection without rupture, malperfusion syndromes, refractory pain, or rapid aortic expansion at the onset or during presentation at the hospital.¹⁸ Patients meeting the following criteria were excluded: were younger than 18 years; had aortic dissection secondary to trauma, iatrogenic injury, or intramural hematoma; or had Marfan syndrome or Ehlers-Danlos syndrome. A flow chart of study population is shown in Figure 1. For the present report, the follow-up period was closed on December 30, 2018. Computed tomography angiography (CTA) examinations of the aorta were routinely performed within 30 days of the TEVAR procedure for the TEVAR group, at 3, 6, and 12 months and yearly thereafter for all qualified patients. A total of 12 patients were lost to follow-up during the study period. Follow-up completeness rate was 95.9%. The median (interquartile range) follow-up duration was 3.2 (1.9-4.2) years in the TEVAR group and 3.8 (1.3-5.6) in the BMT group. The local ethical review board approved this study, and the informed consent was waived for this retrospective study.

Information about the baseline patient characteristics and details of medical and endovascular management were collected from the electronic medical record database of the hospital and outpatient clinic notes. The initial diagnostic and follow-up CTA and digital subtraction angiography images were retrieved from the hospital's imaging archiving system. The anatomic characteristics, the extent of the dissection (using the orifice of the celiac trunk as a divide of the thoracic and abdominal aorta), the thrombosis status of the false lumen, and postoperative aortic-related complications were evaluated retrospectively and documented by 2 experienced radiologists. The final survival state was determined by reviewing hospital admitting notes or death certificate issued by other hospitals.

Patients were divided into 2 groups according to their therapeutic regimen. The TEVAR group consisted of patients with acute uncomplicated TBAD who were treated with TEVAR in addition to medical therapy. The BMT group was made up of patients with acute uncomplicated TBAD who received only medical therapy.

Medical Management

The primary aim of medical therapy was to reduce shear stress on the diseased segment of the aorta by reducing blood pressure and cardiac contractility.⁴ All patients with systolic blood pressure (SBP) >120 mm Hg received active antihypertensive therapy, regardless of the group assignment. Antihypertensive treatment with intravenous beta-blocking agents, nitroglycerin, and calcium-channel blockers was initiated to lower the SBP to between 100 and 120 mm Hg and reduce the heart rate. In patients with refractory hypertension, a combination of several antihypertensives was administered. Pain symptoms in patients with acute uncomplicated TBAD were usually relieved after antihypertensive therapy; if necessary, in our treatment procedure, a narcotic analgesic (morphine hydrochloride) was administered, regardless of the group assignment. After discharge, SBP should be regulated to below 140 mm Hg with lifestyle changes and adequate use of antihypertensive drugs.

TEVAR Procedure

The decision to perform TEVAR in patients with acute uncomplicated TBAD was usually made by the patient and their families based on a full understanding of the advantages and disadvantages of various therapeutic regimens. In brief, the stent-graft procedures were performed in an angiography suite. A 5-French calibrated angiographic pigtail catheter was advanced into the ascending aorta to permit an arteriographic evaluation of the distance between the left subclavian artery (LSA) and the entry tear and the diameter of the aorta where the stent-graft will be implanted. The length of the stent-graft was usually 170 mm, and the diameter was about 5% greater than that of the aorta at stent-graft implantation. In total, 70 U/kg of heparin sodium was administered intravenously. A 22- to 24-French sheath was introduced transfemorally over a 0.035-in stiff

FIGURE 1. Flow chart of study population. Three hundred fifty-seven consecutive patients with acute uncomplicated TBAD were included in this retrospective study. Among them, 191 patients underwent the treatment of TEVAR, and 166 received BMT. A PSM analysis was conducted in this study to minimize selection bias and balance variables. After PSM, 145 pairs of patients were selected for analysis. We found that freedom from all-cause death in the TEVAR group was significantly greater than that of the BMT group ($P = .028$). TBAD, Type B aortic dissection; TEVAR, thoracic endovascular aortic repair; BMT, best medical treatment; PSM, propensity score matching.

guidewire. The stent-graft was then delivered through the sheath and placed within the true lumen of the aorta. After the device was deployed, arteriography was performed to confirm the position of the device relative to the entry tear and to evaluate the size of and flow within the aortic lumens and branch vessels. Two Perclose ProGlide suture-mediated closure devices (Abbott Vascular, Inc, Santa Clara, Calif) were used to close the puncture site of the femoral artery. If the distance between the primary tear and the orifice of the LSA was less than 2 cm, CTA or digital subtraction angiography was performed to assess the vertebrobasilar circulation to know the risk of covering the LSA. The LSA was intentionally covered without reconstruction if the occlusion of the LSA could be compensated sufficiently; otherwise, a reconstruction of the LSA was performed. An intentional coverage of the LSA is permitted, but deliberately covering the left common carotid artery (LCCA) is not permitted. A reconstruction of the LSA or LCCA was performed principally with endovascular chimney technique to secure proximal landing zone length. Adjunctive stent implantation of visceral branches or iliac arteries was performed to reduce the risk of malperfusion when it was deemed necessary based on angiographic evaluation.

Definitions

Procedure success was defined as complete coverage of the primary entry tear without a type I or III endoleak at the end of the procedure. An early adverse event was defined as any complication associated with the dissection occurring in-hospital or 30-day after confirmatory diagnosis. A late

adverse event was defined as any dissection-related severe complication (including rupture, endoleak, new dissection, or retrograde type A aortic dissection [A-AD]) occurring more than 30 days after confirmatory diagnosis. A late intervention was defined as an endovascular repair or surgical procedure which was associated with dissection, and was performed at 1 month after the initial treatment.

Statistical Analysis

Continuous variables are expressed as mean $\pm$ standard deviation or median with interquartile range (25th-75th percentile), whereas categorical variables are presented as frequency and percentages. Statistical comparisons were made with the χ^2 or Fisher exact test for categorical variables. Assumption of normality of continuous data was tested with the Shapiro-Wilk test. If assumption of normality was met, continuous variables were compared using the Student t test, whereas the Mann-Whitney U test was used for nonparametric variables.

Propensity score matching (PSM) analysis was used to minimize selection bias and balance variables. A propensity score was generated for each patient from a logistic regression model using 25 variables, which are listed in Table 1. Two pairs of matched patients (TEVAR or BMT) were obtained using a 1:1 nearest-neighbor matching algorithm with a caliper of 0.1 and without replacement. Balance of the 2 matched groups was evaluated by standardized mean differences in the matching variables. Usually a maximum standardized mean difference of 0.1 or even 0.15 is considered acceptable.¹⁹

TABLE 1. Baseline covariate distribution between acute uncomplicated type B aortic dissection treated with TEVAR and BMT in the unmatched and matched population

Variable	Unmatched population				Matched population			
	TEVAR (n = 191)	BMT (n = 166)	SMD	P value	TEVAR (n = 145)	BMT (n = 145)	SMD	P value
Age, y	53.5 ± 9.8	55.4 ± 11.1	0.181	.088	54.3 ± 10.0	54.9 ± 10.8	0.062	.597
Male	157 (82.2)	127 (76.5)	0.141	.183	113 (77.9)	113 (77.9)	<0.001	1.000
Hypertension	124 (64.9)	107 (64.5)	0.010	.972	93 (64.1)	92 (63.4)	0.014	1.000
Smoking	91 (47.6)	64 (38.6)	0.184	.084	60 (41.4)	60 (41.4)	<0.001	1.000
Drinking	58 (30.4)	34 (20.5)	0.228	.033	40 (27.6)	34 (23.4)	0.095	.501
Diabetes mellitus	6 (3.1)	10 (6.0)	0.138	.189	6 (4.1)	8 (5.5)	0.064	.784
COPD	22 (11.5)	13 (7.8)	0.125	.243	14 (9.7)	11 (7.6)	0.074	.676
Renal insufficiency	6 (3.1)	11 (6.6)	0.162	.123	5 (3.4)	7 (4.8)	0.069	.768
Coronary artery disease	11 (5.8)	16 (9.6)	0.146	.167	11 (7.6)	13 (9.0)	0.050	.831
Hyperlipidemia	8 (4.2)	8 (4.8)	0.030	.774	6 (4.1)	8 (5.5)	0.064	.784
History of stroke	5 (2.6)	6 (3.6)	0.057	.587	2 (1.4)	4 (2.8)	0.097	.680
Atherosclerosis	68 (35.6)	48 (28.9)	0.143	.178	49 (33.8)	45 (31.0)	0.059	.707
Pleural effusion	28 (14.7)	21 (12.7)	0.059	.582	22 (15.2)	17 (11.7)	0.099	.492
Dissection morphology			0.169	.112			0.087	.555
Confined in thoracic aorta	32 (16.8)	39 (23.5)			26 (17.9)	31 (21.4)		
Extended to abdominal aorta	159 (83.2)	127 (76.5)			119 (82.1)	114 (78.6)		
False lumen patency			0.222	.117			0.127	.718
Patent false lumen	117 (61.3)	99 (59.6)			91 (62.8)	87 (60.0)		
Partial thrombosis	74 (38.7)	63 (38.0)			54 (37.2)	57 (39.3)		
Complete thrombosis	0 (0)	4 (2.4)			0 (0)	1 (0.7)		
Maximum diameter of thoracic aorta, mm	3.5 (3.2-3.8)	3.5 (3.3-3.8)	0.023	.945	3.5 (3.2-3.8)	3.5 (3.3-3.8)	0.061	.635
Maximum diameter of abdominal aorta, mm	2.8 (2.5-3.1)	2.7 (2.5-3.1)	0.007	.536	2.8 (2.5-3.1)	2.7 (2.5-3.1)	0.041	.941
Location of the primary entry tear			0.213	.047			0.074	.636
<2 cm from the LSA	42 (22.0)	23 (13.9)			26 (17.9)	22 (15.2)		
>2 cm from the LSA	149 (78.0)	143 (86.1)			119 (82.1)	123 (84.8)		
SBP on admission, mm Hg	140 (128-154)	140 (124-153)	0.117	.363	140 (125-152)	140 (125-154)	0.008	.974
DBP on admission, mm Hg	80 (72-94)	83 (70-92)	0.057	.636	80 (71-92)	83 (70-90)	0.050	.656
LVEF, %	64 (61-66)	64 (60-66)	0.099	.611	65 (62-66)	64 (60-66)	0.078	.636
Creatinine, μ mol/L	74.2 (62.6-88.6)	77.9 (65.2-94.2)	0.204	.124	72.9 (62.6-88.6)	74.7 (65.1-92.6)	0.082	.267
ALT, U/L	24.0 (16.0-47.0)	23.0 (16.0-38.0)	0.072	.223	24.0 (16.0-48.0)	22.0 (16.0-37.0)	0.027	.133
AST, U/L	22.0 (16.0-31.0)	21.0 (15.8-34.0)	0.141	.812	22.0 (16.0-31.0)	20.0 (16.0-29.0)	0.039	.384
Symptoms at presentation			0.114	.562			0.094	.729
Chest and back pain	163 (85.3)	142 (85.5)			124 (85.5)	125 (86.2)		
Abdominal pain	17 (8.9)	11 (6.6)			12 (8.3)	9 (6.2)		
Other symptoms	11 (5.8)	13 (7.8)			9 (6.2)	11 (7.6)		

Categorical variables are reported as frequency and percentage; continuous variables are reported as mean $\pm$ standard deviation or median (25th-75th percentile). *TEVAR*, Thoracic endovascular aortic repair; *BMT*, best medical treatment; *SMD*, standardized mean difference; *COPD*, chronic obstructive pulmonary disease; *LSA*, left subclavian artery; *SBP*, systolic blood pressure; *DBP*, diastolic blood pressure; *LVEF*, left ventricle ejection fraction; *ALT*, alanine aminotransferase; *AST*, aspartate aminotransferase.

For the time-to-event analysis, the primary outcome of interest was mortality, and freedom from mortality was estimated using the Kaplan–Meier survival method and differences in survival curves were analyzed with the log-rank test. Secondary outcomes of interest were aorta-related

adverse event: rupture, retrograde type A-AD, new dissection, type I endoleak, and late intervention. The Cox proportional hazards model on the matched pairs was used to identify predominant risk factors for all-cause mortality. $P < .1$ in the univariate analysis was defined for selecting

TABLE 2. Early outcomes in the unmatched and matched population

Variable	Unmatched population			Matched population		
	TEVAR (n = 191)	BMT (n = 166)	P value	TEVAR (n = 145)	BMT (n = 145)	P value
Hospital stay, d	10.8 ± 2.7	11.2 ± 8.6	.324	10.9 ± 2.8	11.2 ± 8.0	.612
30-d mortality	1 (0.5)	4 (2.4)	.188	1 (0.7)	3 (2.1)	.622
Early events	23 (12.0)	5 (3.0)	.001	17 (11.7)	4 (2.8)	.003
Acute renal failure	1 (0.5)	0 (0)		1 (0.7)	0 (0)	
Type I endoleak	16 (8.4)	NA		12 (8.3)	NA	
Stroke	2 (1.0)	0 (0)		1 (0.7)	0 (0)	
Rupture	0 (0)	4 (2.4)		0 (0)	3 (2.1)	
Retrograde type A-AD	3 (1.6)	0 (0)		2 (1.4)	0 (0)	
Organ failure	1 (0.5)	1 (0.6)		1 (0.7)	1 (0.7)	

Values are mean ± standard deviation or n (%). TEVAR, Thoracic endovascular aortic repair; BMT, best medical treatment; NA, not available; A-AD, type A aortic dissection.

variables for entry into the multivariable regression analysis. Late intervention and aorta-related events were evaluated with a competing risk analysis with all-cause death as a competing risk. Between-group differences were assessed using the Gray test for cumulative incidence estimates.

All of these statistical tests were 2-sided, and the significance level was <.05. Statistical analyses were performed using SPSS, version 25.0 (SPSS, Chicago, Ill) and R 3.6.1 (R Development Core Team, Vienna, Austria).

RESULTS

Baseline Characteristics

After PSM, 2 groups of 145 subjects were obtained. The baseline characteristics before and after matching are listed in Table 1. Before matching, the TEVAR group had more drinkers and had a larger percentage of the distance <2.0 cm between the primary entry tear and the LSA. After matching, no statistically significant differences were observed between the 2 groups in all baseline variables.

TEVAR Procedure

The median time interval between symptom onset and TEVAR in our study was 7 days (interquartile range, 4–11 days) in the unmatched and matched population. In the matched population, the technical success (coverage of the primary tear) was achieved in 143 (98.6%) patients in the TEVAR group: 2 type I endoleaks were confirmed by angiography after TEVAR. A total of 192 stent-grafts were implanted in 145 patients, including 168 stent-grafts implanted in descending thoracic aorta and 24 adjunctive stent-grafts. Among the 168 stent-grafts that were implanted in the descending thoracic aorta, 125 (86.2%) patients received 1 stent-graft each, 17 (11.7%) patients received 2 stent-grafts each, and 3 (2.1%) patients received 3 stent-grafts each. Five different types of stent-grafts were used in the procedure of TEVAR: Talent (Medtronic, Inc, Minneapolis, Minn) was used in 93 patients, E-vita (JOTEC GmbH, Hechingen, Germany) in 27 patients, Zenith (Cook, Bloomington, Ind) in 7 patients, Aegis (Microport, Shanghai, China) in 20 patients, and Ankura (Lifetech

Scientific, Shenzhen, China) in 21 patients. Among the 24 adjunctive stent-grafts, 4 (2.8%) chimney stent-grafts were implanted in the LSA, 4 (2.8%) chimney stent-grafts were implanted in the LCCA, 12 (8.3%) stent-grafts were implanted in the abdominal aorta, 1 (0.7%) stent-graft was implanted in the renal artery, and 3 (2.1%) stent-grafts were implanted in the iliac artery. The LSA was completely covered in 9 (6.2%) patients and partially in 35 (24.1%) patients.

Medical Management

Among the 290 matched patients, 185 (63.8%) patients (BMT group, n = 92; TEVAR group, n = 93) had elevated SBP, which dropped to below 120 mm Hg with antihypertensive treatment during hospitalization. In addition, an aortic CTA scan was used for monitoring the changes of the aortic characteristics during the hospitalization in the medical management group. After discharge, all the patients continued to receive antihypertensive therapy, which helped to regulate blood pressure to below 140/90 mm Hg during the mid- and long-term follow-up.

Early Outcomes

Although there was no statistically significant difference in the 30-day mortality between the TEVAR and BMT groups, the early adverse event rates in the TEVAR group were significantly greater than that of the BMT group (11.7% vs 2.8%; $P = .003$). Details of the early outcomes are listed in Table 2.

The 30-day mortality rate in the TEVAR group was 0.7%. One patient was admitted to the hospital with a sudden stroke 22 days after the TEVAR procedure. The choice of a conservative treatment did not work, and the patient died 1 day after the commencement of the treatment. In addition, 2 mild retrograde type A aortic dissections were treated conservatively and followed up closely. One patient experienced organ failure, but completely recovered after

TABLE 3. Late outcomes in the matched population

Variable	TEVAR (n = 145)	BMT (n = 145)	P value
Freedom from all-cause death, %			.028
1 y	97.2% (92.7-98.9)	94.2% (88.8-97.1)	
3 y	96.4% (91.6-98.5)	88.5% (81.1-93.1)	
5 y	91.9% (81.1-96.7)	82.2% (72.9-88.5)	
Freedom from aortic-related death, %			.044
1 y	97.8% (93.6-99.3)	94.2% (88.8-97.1)	
3 y	97.2% (92.6-98.9)	90.2% (83.3-94.4)	
5 y	94.1% (82.9-98.1)	86.1% (77.5-91.7)	
Cumulative incidence of rupture, %			.024
1 y	2.1% (0.6-5.6)	5.7% (2.7-10.5)	
3 y	2.1% (0.6-5.6)	9.7% (5.2-15.9)	
5 y	5.1% (1.1-14.1)	13.7% (7.8-21.3)	
Cumulative incidence of retrograde type A-AD, %			.610
1 y	2.8% (0.9-6.5)	0.7% (0.1-3.7)	
3 y	3.7% (1.4-8.0)	1.7% (0.3-5.5)	
5 y	3.7% (1.4-8.0)	2.9% (0.7-7.7)	
Cumulative incidence of new dissection, %			.529
1 y	2.1% (0.6-5.6)	2.9% (1.0-6.8)	
3 y	3.6% (1.3-7.7)	3.9% (1.4-8.3)	
5 y	3.6% (1.3-7.7)	5.0% (2.0-10.2)	
Cumulative incidence of type I endoleak, %			NA
1 y	4.9% (2.2-9.3)	NA	
3 y	6.1% (2.8-11.4)	NA	
5 y	13.2% (4.9-25.8)	NA	
Cumulative incidence of late intervention, %			.214
1 y	2.1% (0.6-5.5)	6.6% (3.2-11.6)	
3 y	3.6% (1.3-7.6)	6.6% (3.2-11.6)	
5 y	6.0% (1.9-13.3)	9.0% (4.6-15.1)	

Kaplan–Meier estimates for all-cause mortality and aortic-related mortality. Cumulative incidence estimates for rupture, retrograde type A-AD, new dissection, type I endoleak, and late intervention with death as a competing risk. Parentheses indicate 95% confidence intervals. TEVAR, Thoracic endovascular aortic repair; BMT, best medical treatment; NA, not available; A-AD, type A aortic dissection.

10 days of treatment at the intensive care unit. A total of 12 type I endoleaks were observed in the 30-day follow up period. These patients were left untreated but followed up closely. One patient experienced acute renal failure after the TEVAR procedure but completely recovered after active therapy. No paraplegia or paraparesis was found in these patients.

In the BMT group, the 30-day mortality was 2.1%. Three patients all died of sudden aortic rupture during hospitalization or at home after discharge. One patient experienced organ failure, but he improved before discharge.

Late Outcomes

The late outcomes in the matched population are reported in Table 3. Table 3 reports the freedom from death and the cumulative incidence rates for the aortic-related adverse events at 1, 3, and 5 years. A total of 30 late deaths were reported, including 20 aortic-related late deaths, 19 resulting from aortic rupture and 1 from retrograde type A aortic dissection. A total of 8 deaths were categorized as aortic-unrelated late deaths (cardiac-related deaths, n = 2; cancer-related deaths, n = 3; deaths caused by multiorgan failures, n = 2; death caused by severe injury, n = 1). The reasons for the other 2 deaths were unknown.

The freedom from all-cause death in the TEVAR group at 1, 3, and 5 years was 97.2%, 96.4%, and 91.9%, respectively, and in the BMT group was 94.2%, 88.5%, and 82.2%, respectively. Freedom from all-cause mortality in the TEVAR group was significantly greater than that of the BMT group ($P = .028$) (Figure 2, A). Furthermore, freedom from aortic-related death in the TEVAR group at 1, 3, and 5 years was 97.8%, 97.2%, and 94.1%, respectively, and in the BMT group was 94.2%, 90.2%, and 86.1%, respectively. Freedom from aortic-related mortality in the TEVAR group was significantly greater than that of the BMT group ($P = .044$) (Figure 2, B).

Univariate and multivariable analysis of all-cause death in the matched population are reported in Table 4. Univariate Cox-hazard regression analysis revealed that BMT, older age, complete thrombosis, the distance between the primary entry tear and the LSA <2.0 cm, and greater aspartate aminotransferase and alanine aminotransferase were the significant risk factors for all-cause death. Multivariable Cox-hazard regression analysis demonstrated that the older age (hazard ratio [HR], 1.04; 95% confidence interval [CI], 1.01-1.08, $P = .013$), BMT (HR, 2.33; 95% CI, 1.08-5.05, $P = .032$), and the distance between the primary entry tear and the LSA <2.0 cm (HR, 2.30; 95% CI, 1.06-4.99, $P = .035$) were significant risk factors for all-cause death. In contrast, TEVAR was found to be a significant positive prognostic factor of all-cause death. The cumulative incidence of rupture at 5 years was 5.1% in the TEVAR group and 13.7% in the BMT group. The Gray test revealed that the difference in the cumulative incidence of rupture between the 2 groups was statistically significant ($P = .024$) (Figure 3). Meanwhile, there were no statistically significant differences in the cumulative incidence of retrograde type A-AD and new dissection between the 2 groups ($P = .610$; $P = .529$, respectively). The cumulative incidence of type I endoleak at 1, 3, 5 years in the TEVAR group was 4.9%, 6.1%, 13.2%, respectively.

FIGURE 2. Kaplan–Meier survival analysis in the matched patients who were treated with TEVAR or BMT. The differences between the 2 groups were assessed with log-rank test. A, Freedom from all-cause death between the 2 groups. Freedom from all-cause death in the TEVAR group was significantly greater than that of the BMT group ($P = .028$). B, Freedom from aortic-related death between the 2 groups. Freedom from aortic-related death in the TEVAR group was significantly greater than that of the BMT group ($P = .044$). TEVAR, Thoracic endovascular aortic repair; BMT, best medical treatment.

In the TEVAR group, 6 (4.1%) patients needed reintervention for type I endoleak (2 of 6), abdominal aortic aneurysm expansion (1 of 6), dissection extension (1 of 6), and retrograde type A-AD (2 of 6). In the BMT group, 12 (8.3%) patients needed operation with TEVAR or open surgery, and the reasons were false lumen dilation (9 of 12) and dissection extension (3 of 12). Although there was no statistically significant difference in the cumulative incidence of late intervention between the 2 groups ($P = .214$) (Figure 4), 4 patients in the BMT group were died even after operation, whereas there were no deaths in the TEVAR group.

In subgroup analysis, no statistically significant postoperative differences were observed among patients that required a chimney technique compared with the groups in whom the LSA was covered (Table E1). Meanwhile, no statistically significant postoperative differences were observed among patients of whether to accept adjunctive stent implantation of visceral branches in the TEVAR group (Table E2).

DISCUSSION

A long-standing consensus is that patients with acute uncomplicated TBAD should be treated medically. However, the long-term outcome of acute uncomplicated TBAD

treated with BMT is sobering; more than three-quarters will develop future postdissection aneurysms requiring surgical treatment.²⁰ Since TEVAR was first introduced by Dake and colleagues²¹ in 1994, this procedure has become an effective alternative to surgery for acute complicated TBAD. However, the net benefit of TEVAR in patients with acute uncomplicated TBAD remains a matter of debate. The purpose of our study was to further assess the outcomes of TEVAR in patients with acute uncomplicated TBAD compared with those receiving BMT.

Most previous studies^{9,11,14,22} that reported TEVAR or BMT for TBAD included patients with both complicated and uncomplicated aortic dissections, as well as mixed cases of acute and chronic dissections. Meanwhile, several previous^{3,12,13,23} studies that compared TEVAR with BMT for acute TBAD reported that the 30-day mortality ranged between 0.5% and 20.0% in the TEVAR group and between 0% and 10.6% in the BMT group. In the present study, the 30-day mortality was 0.7% in the TEVAR group and 2.1% in the BMT group, which was consistent with the results from previous studies. In addition, 2 previous retrospective studies^{12,23} reported a lower 30-day mortality in TEVAR and BMT for acute TBAD, 0.5% and 0%, respectively. Furthermore, the ADSORB trial¹⁷ (Acute Dissection: Stent graft OR Best medical therapy), the first

TABLE 4. Univariate and multivariable analysis of all-cause death in the matched population (Cox hazard analysis)

Variable	Univariate analysis		Multivariate analysis	
	HR (95% CI)	P value	HR (95% CI)	P value
BMT	2.31 (1.07-5.00)	.033	2.33 (1.08-5.05)	.032
Age, y	1.05 (1.01-1.08)	.011	1.04 (1.01-1.08)	.013
Male	1.04 (0.45-2.38)	.932		
Hypertension	1.33 (0.67-2.64)	.408		
Smoking	1.15 (0.58-2.27)	.686		
Drinking	0.56 (0.23-1.36)	.199		
Diabetes mellitus	1.20 (0.29-5.03)	.799		
COPD	1.35 (0.52-3.49)	.538		
Renal insufficiency	0.55 (0.75-4.02)	.554		
Coronary artery disease	0.68 (0.16-2.85)	.597		
Hyperlipidemia	0.04 (0.00-6.62)	.214		
History of stroke	1.64 (0.39-6.89)	.499		
Atherosclerosis	1.15 (0.57-2.33)	.694		
Pleural effusion	0.45 (0.14-1.48)	.187		
Dissection morphology	1.35 (0.63-2.89)	.447		
False lumen patency				
Patent false lumen	Ref	Ref	Ref	Ref
Partial thrombosis	1.64 (0.81-3.31)	.169	1.68 (0.83-3.42)	.151
Complete thrombosis	5.61 (0.74-42.72)	.096	2.28 (0.29-17.91)	.435
Maximum diameter of thoracic aorta, mm	1.49 (0.80-2.77)	.205		
Maximum diameter of abdominal aorta, mm	1.20 (0.61-2.34)	.595		
Location of the primary entry tear	2.20 (1.01-4.77)	.046	2.30 (1.06-4.99)	.035
SBP on admission, mm Hg	0.99 (0.98-1.01)	.394		
DBP on admission, mm Hg	1.00 (0.99-1.03)	.372		
LVEF, %	1.00 (0.94-1.06)	.999		
Creatinine, μ mol/L	1.00 (0.99-1.01)	.804		
ALT, U/L	0.97 (0.94-1.00)	.019	0.97 (0.94-1.01)	.096
AST, U/L	0.97 (0.95-1.00)	.079	1.00 (0.97-1.02)	.778
Symptoms at presentation				
Chest and back pain	0.81 (0.24-2.67)	.724		
Abdominal pain	2.11 (0.46-9.63)	.335		
Other symptoms	Ref	Ref		

HR, Hazard ratio; CI, confidence interval; BMT, best medical treatment; COPD, chronic obstructive pulmonary disease; SBP, systolic blood pressure; DBP, diastolic blood pressure; LVEF, left ventricle ejection fraction; ALT, alanine aminotransferase; AST, aspartate aminotransferase.

randomized trial on acute dissection, compared BMT with the combination treatment of thoracic stent grafting with BMT for patients with acute uncomplicated TBAD, and it reported that there were no deaths in either the TEVAR or BMT group during the first 30 days. These studies with low mortality had common patient inclusion criteria that was patients with uncomplicated TBAD.

In this study, the early adverse event rates were 11.7% in the TEVAR group and 2.8% in the BMT group. The early adverse event rates in the BMT group were consistent with findings from previous studies.^{24,25} Previous studies reported that the early adverse event rates of TEVAR for complicated TBAD were 2.4%~33.3%,²⁶⁻²⁸ whereas there were relatively few reports about the early adverse

FIGURE 3. The cumulative incidence of the aortic-related events with all-cause death as a competing risk in the matched patients who were treated with TEVAR or BMT. The differences were assessed with the Gray test. The cumulative incidence of rupture in the BMT group was significantly greater than that of the TEVAR group ($P = .024$). TEVAR, Thoracic endovascular aortic repair; BMT, best medical treatment.

FIGURE 4. The cumulative incidence of the late intervention with all-cause death as a competing risk in the matched patients who were treated with TEVAR or BMT. The difference was assessed with the Gray test. The difference in the late intervention between the two groups was not statistically significant. TEVAR, Thoracic endovascular aortic repair; BMT, best medical treatment.

event rates of TEVAR for uncomplicated TBAD. Recently, a multicenter retrospective study reported that the early adverse event rates of TEVAR and BMT in the treatment of acute uncomplicated TBAD were 10.5% and 4.5%, respectively.¹² This result was close to our finding, but the early adverse event rates in the TEVAR group in our study were significantly greater than that of in the BMT group. The most common complications during and after TEVAR included endoleak, retrograde type A dissection, cerebral ischemia, and paraplegia.²⁹⁻³¹ Type-I endoleak is a matter of concern in all studies on thoracic endografting and is reported quite frequently. In our study, 12 cases (8.3%) with type-I endoleak were observed in the early stage. Interestingly, we found that 8 (66.7%) of these cases were used the same brand of the stent, that was the E-vita stent-grafts. Zipfel and colleagues³² also reported previously that the use of E-vita stent-grafts resulted in a greater incidence of 18% early proximal endoleaks, compared with the authors' Talent experience with an incidence of 10% persistent endoleaks. Despite the high rate of early adverse events after TEVAR, most of them appeared to be mild or transient. No significant expansion of early endoleak was reported at 1-year follow-up, and only 1 of the patients experiencing late death had an early endoleak.

Survival rates in patients with TBAD after TEVAR have been reported to range from 81.5% to 91.9% at 1 year and from 76% to 89.2% at 5 years.^{9,12,33,34} In medically treated patients, survival rates ranged from 84% to 90.2% at 1 year

VIDEO 1. The process of admission diagnosis in a patient with acute uncomplicated TBAD, the treatment for this patient with TEVAR procedure, and the patient's follow-up. TBAD, Type B aortic dissection; TEVAR, thoracic endovascular aortic repair. Video available at: [https://www.jtcvs.org/article/S0022-5223\(19\)40469-8/fulltext](https://www.jtcvs.org/article/S0022-5223(19)40469-8/fulltext).

and from 60% to 86.8% at 5-year.^{9,12,34} Although the ADSORB trial is the first randomized trial on acute dissection, it was underpowered for survival and had a cut-off at 1-year follow-up. The INSTEAD-XL (Investigation of Stent Grafts in Aortic Dissection with Extended Follow-Up) trial is the only prospective randomized trial to investigate the long-term outcomes of TEVAR for uncomplicated aortic dissections.³⁵ It showed that TEVAR improved the 5-year overall and aorta-specific survival for patients with uncomplicated aortic dissections: the overall survival (88.9% vs 80.7%) and aorta-specific survival (93.1% vs 80.7%) at 5-year were significantly greater with TEVAR than with optimal medical treatment alone. In the present study, the cumulative 5-year survival and aorta-related survival for TEVAR were 91.9% and 94.1%, respectively, and for BMT were 82.2% and 86.1%, respectively. These results in our study were close to the results of INSTEAD study. Therefore, the results of our study confirmed the results of INSTEAD study that the treatment of TEVAR improved the survival for patients with uncomplicated aortic dissections compared with BMT alone.

As for late adverse events in our study, although the difference in the number of complications between the 2 groups was not statistically significant, the BMT group appeared to have more fatal complications. Type I endoleak (6.9%) was the most common complication in the TEVAR group. However, type I endoleak was not a permanent complication of TEVAR, and 4 type I endoleaks disappeared in the follow-up CTA imaging. In the BMT group, the most common complication was aortic rupture (9.7%). The cumulative incidence of this complication in the BMT group was significantly greater than that of the TEVAR group. In addition, although there was no statistically significant difference in the cumulative incidence of late intervention between the 2 groups, 4 patients in the BMT group died even after operation, whereas there were no deaths in the TEVAR group after reoperation. It indicated that the prognosis of patients after reintervention in the TEVAR group may be better than that of in the BMT group.

Study Limitations

Our study has several limitations. First, our study was retrospective, and potential selection bias in our population could not be completely avoided even after PSM analysis. Second, although the sample size was large enough, and the follow-up period was comparatively long, the relatively large proportion of patients in recent years may be linked partially to good results. Lastly, various types and constructions of stent grafts and both improved technical expertise and stent-graft design may impact our findings.

CONCLUSIONS

Although there were many cases of early adverse events after TEVAR in our investigation, most of them were mild and transient. In a long-run perspective, TEVAR for acute uncomplicated TBAD patients showed an improved mid-term survival and fewer late aortic ruptures compared with BMT alone. Therefore, TEVAR may be considered as the first option to improve the late outcomes in patients with acute uncomplicated TBAD (Video 1).

Conflict of Interest Statement

Authors have nothing to disclose with regard to commercial support.

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Key Words: aortic dissection, endovascular procedures, outcomes

TABLE E1. Postoperative outcomes of different treatments for the left subclavian artery in the TEVAR group

Variable	Chimney stent	Completely covered	Partially covered	Not covered	P value
Number in TEVAR, n (%)	4 (2.8)	9 (6.2)	35 (24.1)	97 (66.9)	
All-cause death, n (%)	0 (0)	0 (0)	2 (1.4)	7 (4.8)	.663
Cumulative events, n (%)	1 (0.7)	1 (0.7)	8 (5.5)	13 (9.0)	.830

Values are n (%). The differences were assessed with log-rank test. *TEVAR*, Thoracic endovascular aortic repair.

TABLE E2. Postoperative outcomes of whether to accept adjunctive stent implantation of visceral branches in the TEVAR group

Variable	Received adjunctive stent	Without adjunctive stent	P value
Number of patients in the TEVAR group, n (%)	12 (8.3)	133 (91.7)	
All-cause death, n (%)	0 (0)	9 (6.2)	.352
Cumulative events, n (%)	2 (1.4)	21 (14.5)	.937

Values are n (%). The differences were assessed with log-rank test. *TEVAR*, Thoracic endovascular aortic repair.