Mid-term outcomes of thoracic endovascular aortic repair for complicated type B aortic dissection

Salih Salihi , Hakan Saçlı , Halil İbrahim Erkengel , İbrahim Kara

Department of Cardiovascular Surgery, Sakarya University Training and Research Hospital, Sakarya, Turkey

ABSTRACT

Objectives: The aim of this study was to evaluate the mid-term outcomes of thoracic endovascular aortic repair (TEVAR) of complicated type B aortic dissection.

Patients and methods: This retrospective study included a total of 29 consecutive patients (27 males, 2 females; mean age 61.1±11.8 years; range, 34 to 80 years) who underwent TEVAR due to complicated type B aortic dissection at our center between March 2015 and December 2018. All pre-, intra-, and postoperative data were collected. Surgical and discharge notes were reviewed.

Results: Of the patients, 27 had hypertension and seven had coronary artery disease. The mean maximum aortic diameter was 50.5±7.7 mm. Suspicion of impending rupture was the most (n=13) associated complication with type B aortic dissection. Six patients (20.7%) had rupture and 10 patients (34.5%) had uncontrolled hypertension. The procedure was performed under elective conditions in 18 patients (62.1%) and under emergency setting in 11 patients (37.9%). Early mortality was developed in one patient (3.4%) due to low cardiac output syndrome. The mean follow-up was 25±11 months. Late mortality occurred in two patients (6.9%) due to lung cancer and sepsis. The overall survival rate was 86.1±9.8% and freedom from aortic re-intervention was 88.8±7.5% at 50 months.

Conclusion: Our study results show that TEVAR is a safe procedure associated with good postoperative outcomes, and outstanding mid-term results in complicated type B aortic dissection.

Keywords: Aortic dissection, endovascular aortic repair, thoracic aorta.

Aortic dissection is the most frequent and catastrophic manifestation of acute aortic syndrome. Stanford type B aortic dissection (TBAD) originates in the descending thoracic aorta without retrograde extension into the ascending aorta.[1] Type B aortic dissection may be classified as uncomplicated or complicated. Due to the high mortality rates associated with surgery, stable patients with uncomplicated type B dissection has traditionally been treated with optimal medical therapy (OMT) including aggressive anti-hypertensive treatment.[1] Complicated TBAD is defined by the presence of at least one of the following: aortic rupture or impending rupture, uncontrolled hypertension despite full medication, persistent abdominal or chest pain, early aortic expansion, and

malperfusion syndrome involving visceral, renal, or extremity ischemia.

Since open surgical repair (OSR) has several disadvantages include a long operation time, aortic clamping, and neurological complications, thoracic endovascular aortic repair (TEVAR) is considered as the gold standard for complicated TBAD, and current guidelines recommend TEVAR for complicated TBAD patients as Class I indications.[2-4] The benefits of TEVAR include low-dose heparin use, less blood product use, shorter hospital stays, avoidance of thoracotomy or sternotomy incision, and decreased end-organ ischemia.[5] On the other hand, there are several studies maintaining that five-year

reintervention rates are much higher in patients undergoing TEVAR, compared to OSR.[6,7]

In the present study, we aimed to evaluate the mid-term outcomes of TEVAR of complicated TBAD patients.

PATIENTS AND METHODS

This retrospective study included a total of 29 consecutive patients (27 males, 2 females; mean age 61.1±11.8 years; range, 34 to 80 years) who underwent TEVAR due to complicated TBAD at our center between March 2015 and December 2018. Patients with TBADs were decided to be complicated if one or more of the following complications were present: *(i)* ongoing persistent chest pain, despite maximal medical therapy; *(ii)* radiographic or clinical evidence of aortic rupture or impending rupture; *(iii)* malperfusion syndrome involving visceral, renal, or extremity ischemia; and *(iv)* symptomatic presentation with an aortic diameter greater than 5 cm or early aortic expansion. All patients were operated by a single surgical team. All pre-, intra-, and postoperative data were collected. Surgical and discharge notes were reviewed. A written informed consent was obtained from each patient. The study protocol was approved by the Sakarya University Training and Research Hospital Ethics Committee (No.71522473/050.01.04/281, Date:23/11/2018). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Preoperative planning

Initially, all patients were subjected to medical history and full physical examination. Electrocardiography, chest X-ray, and echocardiography were performed for the evaluation of cardiac functions and valve pathologies. All patients were evaluated by a 3-mm section thoracoabdominal computed tomography (CT) angiography with three-dimensional reformatting. The CT angiography should be continued from the chest to include the abdomen and pelvis too, so that an assessment of the iliac arteries can be made to ensure suitable access for passage of the stent-graft device. The location and size of initial entry and the extent of aortic dissection were examined. The size and location of the disease segment, presence of calcification or thrombus in the vessel wall, presence of malperfusion, and the structure of the access arteries were examined.

Operative techniques

The procedure was performed under general anesthesia in an angiography room by the TEVAR team including two cardiovascular surgeons and an anesthesiologist. Vascular access was obtained by a small groin "bikini" incision through the unilateral common femoral artery and with the installation of a guidewire from the other femoral artery. After the administration of systemic heparinization (100 IU/kg), wire access was gained into the ascending aorta and exchanged for a stiff wire to allow tracking of the device. After placement of the endograft, angiography was performed with power injection and respiratory arrest by anesthesia to allow for precise graft positioning. Endograft size was selected with 5 to 10% oversize of the calculated diameter of the aorta in the proximal non-dissected aorta and the true lumen in the distal landing zone. We placed a single 15- to 20-cm-long device. When needed, a second stent-graft was placed. Completion angiography was, then, performed to assess for endoleaks; the sheath and device were removed; and the arteriotomy was closed. In general, we avoided post-deployment angioplasty. Inflating the aortic balloon was performed, only if a large type IA proximal endoleak was documented, and only at the proximal landing zone. E-vita THORACIC 3G (JOTEC GmbH, Hechingen, Germany) stent grafts were used in 22 patients and Valiant Captivia (Medtronic Vascular, Santa Rosa, CA, USA) stent grafts in seven patients.

After the procedure, all patients were carefully monitored in the cardiac surgery intensive care unit (ICU). The mean blood pressure was strictly kept around 70 mmHg to prevent retrograde aortic dissection or spinal cord ischemic injury. In cases involving important aortic side branches (e.g. left subclavian artery), we closed the supra-aortic branches in the region of the proximal junction of the endovascular graft. The subclavian artery was covered as needed to obtain an adequate (>2 cm) non-dissected landing zone proximal to the entry tear. A hybrid approach involving surgical reconstruction of the supra-aortic branches and endovascular lesion repair was performed.

Follow-up

All patients were postoperatively evaluated with CT angiography at one month (first follow-up) and in the mid-term (second follow-up). Mid-term follow-up was obtained at an average of 25±11 months. The aortic diameter was assessed just below the distal end of the stent-graft. Complications such as endoleak and graft migration were investigated during follow-up visits using contrast-enhanced thoracic CT. Follow-up

data were analyzed using cardiology and cardiac surgery outpatient follow-up notes, primary care and institutional computer-based databanks, and telephone interviews. Mortality within the first 30 days following the procedure was defined as operative mortality.

Statistical analysis

Statistical analysis was performed using the IBM SPSS version 25.0 software (IBM Corp., Armonk, NY, USA). Continuous variables were expressed in mean ± standard deviation (SD), unless noted otherwise, while categorical variables were expressed in number and frequency. Survival and freedom from adverse events were estimated using the Kaplan-Meier method.

RESULTS

Of all patients, 27 (93.1%) had hypertension, three (10.3%) had diabetes, 14 (48.3%) had chronic obstructive pulmonary disease, and seven (24.1%) had coronary artery disease (CAD). The mean maximum aortic diameter was 50.5±7.7 mm. Suspicion of impending rupture was the most (n=13, 44.8%) associated complication with TBAD. Six patients (20.7%) had rupture and 10 patients (34.5%) had uncontrolled hypertension. Baseline demographic and clinical characteristics of the patients are summarized in Table 1.

The procedure was performed under elective conditions in 18 patients (62.1%) and under the emergency setting in 11 patients (37.9%). We used one graft for each patient, except for one patient in whom a second stent graft was placed distally to eliminate a type IB endoleak. The mean length of the stent graft employed was 194.1±35.1 cm. Supra-aortic arch bypass was carried out in one patient (3.4%) who was treated with landing Zone 1 TEVAR. No immediate open surgical conversions were needed. Stent graft and aortic characteristics are listed in Table 2. The ostium of the left subclavian artery was covered in nine patients (31%) to obtain an adequate proximal landing zone. The mean length of ICU stay was 1.8±1.5 days and the mean length of ward stay was 7±3.4 days.

The early and late postoperative outcomes of all patients are presented in Table 3. Early mortality was developed in one patient (3.4%) due to low cardiac output syndrome who had CAD. One patient had a temporary pa raparesis, which resolved within 15 days. Pulmonary complications occurred in seven patients (24.1%). Renal insufficiency defined as serum creatinine ≥2.5 mg/dL) occurred in two patients (6.9%) and none of these patients required hemodialysis.

The mean follow-up was 25±11 months. Late mortality occurred in two patients (6.9%) due to lung cancer and sepsis. Cumulative survival analysis of patients was assessed by Kaplan-Meier survival

Table 1. Demographic and clinical characteristics of patients (n=29)			
Variables	n	%	Mean±SD
Age (year)			61.1±11.8
Gender			
Male	27	93.1	
Body mass index (≥30 kg/m²)	1	3.4	
Preoperative LVEF (%)			58±7
Smoking history	19	65.5	
Associated diseases			
Hypertension	27	93.1	
Diabetes mellitus	3	10.3	
Chronic obstructive pulmonary disease	14	48.3	
Peripheral vascular disease	4	13.8	
Coronary artery disease	7	24.1	
Dialysis-requiring chronic renal failure	1	3.4	
Previous cardiac operations	1	3.4	
Perioperative aorta diameter (mm)			50.5±7.7
Complications associated with type B dissection			
Rupture	6	20.7	
Suspected rupture	13	44.8	
Malperfusion	2	6.9	
Uncontrolled hypertension	10	34.5	
Severe refractory pain	9	31	
SD: Standard deviation; LVEF: Left ventricle ejection fraction.			

| Table 2. Operative data (n=29)			
Variables	n	%	Mean±SD
Time from onset to TEVAR			
Acute	11	37.9	
Chronic	18	62.1	
Employed stent graft			
One	28	96.6	
Two	1	3.4	
Length of the stent graft (mm)			194.1±35.1
Proximal landing zone			
Zone 1	1	3.4	
Zone 2	8	27.6	
Zone 3	15	51.7	
Zone 4	5	17.3	
Supra-aortic arch bypass	1	3.4	
Coverage of LSA	9	31	
Stent graft devices			
E-vita thoracic 3G	22	75.9	
Medtronic valiant captivia delivery system	7	24.1	
Intensive care unit stay (day)			1.8±1.5
Hospital stay (day)			7±3.4
SD: Standard deviation; TEVAR: Thoracic endovascular aortic repair; LSA: Left subclavian artery.			

Table 3. Early and late morbidity and mortality (n=29)

| Variables	n	%
Early (<30 days)		
In hospital mortality	1	3.4
Low cardiac output syndrome	1	3.4
Pulmonary complications	7	24.1
Postoperative renal failure*	2	6.9
Healing problem in femoral incision	3	10.3
Superficial infection	2	6.9
Seroma	1	3.4
Late (25±11 month)		
Mortality	2	6.9
Endoleak		
Endoleak 1A	1	3.4
Endoleak 1B	2	6.9
Graft thrombosis	0	0
Graft migration	0	0

* A creatinine level of >2.5 mg/dL.

analysis. The overall survival rate was 86.1±9.8% at 50 months (Figure 1).

Wound healing problem in the femoral incision was observed in three patients (10.3%). Type IB endoleak developed in three patients (10.3%) at 18, 20, and 24 months, postoperatively. No additional procedure was
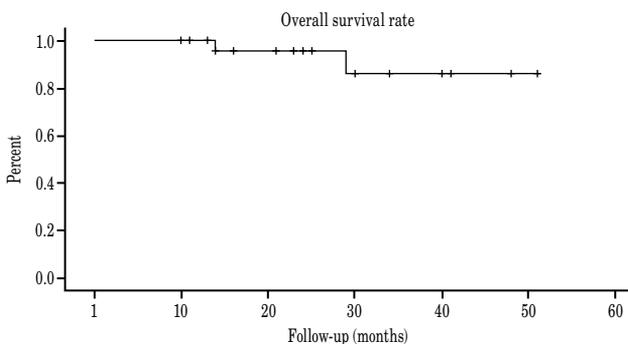
Figure 1. Kaplan-Meier survival analysis showing overall survival after thoracic endovascular aortic repair.
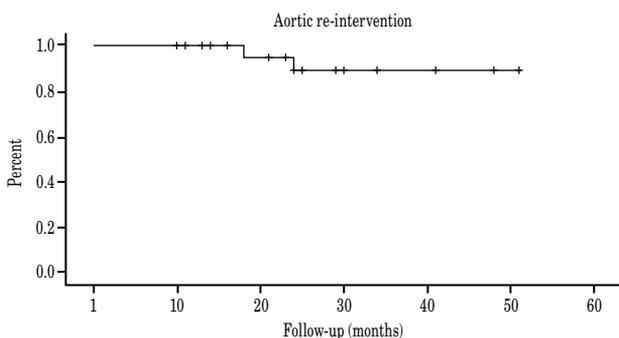
Figure 2. Kaplan-Meier analysis of freedom from aortic reintervention.

performed in one patient, while two patients (6.9%) had aortic reintervention with TEVAR. The freedom from aortic re-intervention rate was 88.8±7.5% at 50 months (Figure 2). No stent migration, dislocation or graft thrombosis was documented in our patients postoperatively.

DISCUSSION

In this study, the midterm outcomes of TEVAR for complicated TBAD were reported. The early mortality was developed in one patient due to CAD. The overall survival rate was 86.1±9.8% and freedom from aortic re-intervention was 88.8±7.5% at 50 months.

Type B aortic dissection is a life-threating disease which needs immediate or delayed treatment. Uncomplicated TBAD has classically been treated with medical therapy. The role of TEVAR in the setting of uncomplicated TBAD is still challenging. In the Investigation of Stent Grafts in Aortic Dissection (INSTEAD) trial including patients with uncomplicated TBAD and comparing combined TEVAR and OMT (TEVAR+OMT) with OMT alone, there was no significant difference in the two-year survival rates between the groups.[8] However, the INSTEAD-XL trial which was conducted for extended for late follow-up showed that TEVAR in addition to OMT was beneficial in terms of freedom from aortic adverse events.[9]

Aortic rupture, persistent pain, uncontrolled hypertension, early aortic expansion and malperfusion are the major causes of early mortality in TBAD patients.[10] Of note, TBAD patients undergoing OSR or TEVAR have a significant survival advantage over those treated medically alone.[11] As OSR for complicated TBAD has been accompanied by high morbidity and mortality,[12,13] TEVAR is recommended in the treatment for these patients, particularly in elderly and comorbid patients.[4] Jonker et al.[14] confirmed the beneficial results of TEVAR for acute complicated TBAD with an in-hospital mortality of 4%, 40% and 33% for TEVAR, OSR, and OMT patients, respectively.[14] In our study, the in-hospital mortality was seen in only one patient (3.4%) due to CAD.

In the present study, two patients were treated due to malperfusion involving extremity ischemia. In case of malperfusion, coverage on the entry tear with the stent graft allows re-expansion of the true lumen and increased organ perfusion.[15,16] Coverage of the subclavian artery without revascularization

is generally well-tolerated, but may lead to left arm ischemic symptoms in up a minority of patients.[17] In our study, the ostium of the left subclavian artery was covered in nine patients (31%) to obtain a healthy proximal landing zone. In these patients, coverage of the left subclavian artery without revascularization was well-tolerated without no ischemic symptoms in the patients.

Acute kidney injury frequently occurs after catheter-based interventional procedures and has been shown to increase early morbidity and mortality.[18] The incidence of acute kidney injury after TEVAR is variable. Ertugay et al.[19] reported renal complications in three patients (12%) undergoing TEVAR due to acute aortic syndrome, while Karakisi et al.[20] reported acute renal failure in two patients (8%). In our study, renal insufficiency defined as serum creatinine ≥2.5 mg/dL occurred in two patients, and none of these patients required hemodialysis.

Currently, several meta-analyses have demonstrated favorable short and mid-term results in patients with complicated TBAD treated with TEVAR.[21,22] However, complications with TEVAR, such as endoleaks and graft migration, may occur more easily than with OSR.[23] In a study, aortic reintervention was required in 10.8% (4 of 37) in the complicated acute TBAD treated with TEVAR.[10] Reinterventions in these patients were due to type A aortic dissection in two patients, type I endoleak in one patient, and ruptured descending aorta in one patient. In our study, aortic reintervention was required in two patients (6.9%) due to type IB endoleak. There was no graft migration or graft thrombosis in our patients during the follow-up period.

Our techniques of groin incision have evolved over the years. We used a classic femoral incision in the earlier part of our experience. Recently, we have favored the "bikini" incision which is more comfortable for patients with less complications than the conventional technique. In our study, there were three patients with wound healing problem in the femoral incision and two of them occurred before the "bikini" incision.

Nonetheless, this study is limited by its retrospective design, small sample size, and mid-term follow-up results over a 10-year period. Therefore, further large-scale, long-term, prospective studies are needed to confirm these findings.

In conclusion, our study results suggest that TEVAR is a safe procedure associated with good postoperative outcomes and outstanding mid-term results in complicated TBAD.

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