

Thoracic Endovascular Stent Graft Implantation Efficacy

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Abstract

Objectives: Thoracic aortic aneurysm (TAA) is an uncommon disease with an incidence of 10.4 per 100,000 and dissection is the major complication of TAA. The treatment of aortic diseases is surgery. In recent years, endovascular stent graft (EVSG) application has been performed for many reasons, especially due to its low complications in the treatment of aortic aneurysm and dissection. The aim of this study is to evaluate the efficacy, treatment results, and complications EVSG implantation.

Methods: A total of 34 patients with thoracic aortic disease who underwent stent grafting between August 2004 and January 2011 were included in the study. The patients' diagnoses and risk factors were recorded. Complications of the procedure and the presence of postprocedural leakage were evaluated. The patients were followed up with computed tomography angiography.

Results: Of the 34 patients who underwent the procedure, 16 had no early, late complications and no leakage, whereas eight required additional stenting and other intervention. During follow up three patients showed acute cerebral infarction and four patients have hospital infections. A total of 7 patients had endoleaks occurred and repair with additional interventions. The average hospital stay is 5.8 days. The mortality rate in the hospital is 11.7%.

Conclusion: The EVSG treatments of acute and chronic thoracic aortic diseases in appropriate patients is an alternative and safe method to surgery with high technical success, low complication rates.

Keywords: Endovascular stent-graft, thoracic aortic aneurysm, computed tomography, anjiography

Introduction

Thoracic endovascular stent graft (EVSG) is the preferred treatment option for thoracic aortic pathologies and consists of placing a stent-graft in the pathological area to restore the lumen. In the last thirty years, the effectiveness of EVSG, especially in type B aortic dissection and aneurysms, has been proven by numerous studies.¹⁻¹² In recent years, studies have been conducted to evaluate the effectiveness of different types and brands of stent grafts.¹³⁻¹⁵ Additionally, studies by teams performing EVSG with new and different techniques are of interest.^{16,17}

In this study, we tried to present the treatment effectiveness and results of EVSG implantation using different stent-grafts in 34 patients with type B aortic dissection and aneurysm, and especially to emphasize the importance of the complication profile and management.

Methods

Study Population

A total of 34 patients with thoracic aortic disease underwent stent graft implantation. Twenty-six of these patients were male and 8 were

female, and their ages ranged from 27 to 81 years (mean age: 64.91 years). The patients' comorbidities, risk factors, post-procedure follow-up, early and late results of the procedure, early and late complications of the procedure, and treatment of complications were evaluated retrospectively. Additionally, the necessity of emergency surgery or additional interventions was investigated. The study inclusion and exclusion criteria are defined below. Criteria for inclusion in the study;

- Patients with complicated and uncomplicated type B aortic dissection, rupture, penetrating ulcer and intramural hematoma
- Degenerative or traumatic type B aneurysms.

Exclusion criteria from the study;

- Patients with Stanford type A aortic dissection, rupture, penetrating ulcer and intramural hematoma
- Patients with chronic dissection associated with connective tissue disease

Ethical approval for the study was granted by the Ethics Committee of Başkent University Faculty of Medicine (code: KA 12-04, date: 16.02.2012).

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Evaluation Before Endovascular Procedure

All procedures were performed in the angiography unit, under appropriate sterile conditions, by a multidisciplinary team consisting of an interventional radiologist, cardiovascular surgeon and anesthesiologist. All patients were administered local anesthesia and sedation. Before the procedure, patients were evaluated for suitability for aneurysm and dissection repair by computed tomography (CT) angiography (CTA) (Sensation 16, Siemens, Germany) and digital subtraction angiography (Siemens Multistar TOP). Detailed measurements were obtained to determine graft type and dimensions. Iliac and femoral arteries were evaluated for compatibility. Parameters such as the diameters of the false and true lumens of the aorta, vascular calcification, the presence of intraluminal thrombus, and the length of the aneurysmal segment were measured. Informed consent was obtained from all patients after discussion of potential complications.

Endovascular Procedure

After the patient was placed on the angiography table, vascular sheaths were applied to appropriate anatomical areas to facilitate thorax angiography (Table 1). During angiography, segment length and iliac arteries requiring repair (especially if there was potential iliac artery stenosis or angulation on preprocedural CT) were evaluated according to predefined criteria. For aneurysm repair, measurements were made to ensure that the proximal and distal graft implantation sites adhere to intact vessel segments, and the graft diameter was selected to be 20% larger than the measured vessel diameter. After selecting the appropriate stent graft material and confirming vascular access, the patency of the left subclavian artery was assessed. The right common femoral artery was then exposed and accessed via incision. The left femoral artery was incised in five patients (15%) (Table 1). A guidewire was advanced into the aortic arch through an appropriately sized vascular sheath, followed by proper positioning of the sheath for stent graft placement. The stent was directed to the targeted location with the graft delivery system and the graft was positioned correctly. A follow-up angiography was performed to confirm stent placement and assess for any endoleak.

For aneurysm repair, measurements were made to ensure that the proximal and distal graft implantation sites adhere to intact vessel segments, and the graft diameter was selected to be 20% larger than the measured vessel diameter. After selecting the appropriate stent graft material and confirming vascular access, the patency of the left subclavian artery was assessed. The common femoral artery was then exposed and accessed via incision. A guidewire was advanced into the aortic arch through an appropriately sized vascular sheath, then the appropriate sheath for the stent graft was positioned. The stent was directed to the targeted location with the graft delivery system and the graft was positioned correctly. A follow-up angiography was performed to confirm stent placement and assess for any endoleak. Once

completed, the vascular sheath was removed and the femoral artery was repaired and closed.

Endovascular Prosthesis

A total of 50 stent grafts were placed in the patient cohort. Stent graft systems used included Medtronic Valiant Captiva, Gore TAG, Jotec E-vita® Thoracic Stent Graft System, and Medtronic [R] Talent stents.

In cases where lesion extension was necessary, the left subclavian artery was occluded in 2 patients with thoracic aneurysms and in 7 patients who underwent dissection. In 1 patient with chronic aortic dissection, planned occlusion of the left subclavian artery was postponed after angiography detected insufficient flow in the right vertebral artery due to atherosclerotic changes. In this case, the left subclavian artery patency was preserved initially, and the occlusion was completed in the next session after the left carotid-left subclavian artery transposition.

Statistical Analysis

Normally distributed continuous variables such as age and gender, were expressed as median, standard deviation, and range values. Imaging findings were summarized descriptively using absolute counts and percentages based on the final consensus interpretations. Statistical analysis was performed with Microsoft Excel.

Results

Seventeen type B aneurysms and 17 type B aortic dissections were included in the study. Four (24%) of the aortic aneurysms were ruptured (Figure 1). Of the unruptured aneurysms, 4 were saccular (31%) and 9 (69%) were fusiform aneurysms. Only one of the saccular and fusiform aneurysms had associated ulcerated plaques. 83% (n=14) of the dissection patients had acute dissection and 3 of them (21%) had traumatic dissection.

Except for patients with traumatic dissection, all patients had at least one accompanying chronic disease (Table 2). The most common disease accompanying the patients was hypertension. 76% of aneurysm patients and 82% of dissection patients had hypertension. Smoking was higher in aneurysm patients (n=7) than in dissection patients (n=3). One of the patients with traumatic aortic dissection had multiple rib and vertebral fractures and splenic rupture. This patient underwent splenectomy before graft placement.

No early complications or early endoleaks were observed in 16 of 34 patients who received endovascular treatment during an average

Table 1. The vascular structures used for the access of stent graft for angiography in the endovascular stent graft procedure

	Angiography access	Stent graft access (surgical cutdown)
Right axillary artery	18	-
Left axillary artery	7	-
Right main femoral artery	5	29
Left main femoral artery	4	5



Figure 1. In thoracic aortography (a) ruptured aneurysm, (b) the image of the same patient after the procedure

follow-up period of 10 months. Complications after EVSG procedure are shown in Table 3.

The most common complication was late leakage (n=7, 21%). Leak was most common in patients with unruptured aneurysms (n=5, 71%). The minimal type 1 leak seen in three of these patients resolved during follow-up. In one of the other two patients, type 2 leakage originating from the intercostal arteries resolved over time. In the other, a new aneurysm developed two years after treatment and required an additional stent. However, type 1 leak occurred due to stent migration, which resolved after placement of a third stent. Subsequently, type 2 leakage from the intercostal arteries was noted during late phase control angiography, but no additional intervention was performed because there was no sign of further leakage at follow-up.

In the only acute dissection patient in whom we detected a leak, balloon angioplasty was performed to address the leak and the leak was successfully resolved. However, the same patient later developed a type 2 leak from the closed subclavian artery and closed on its own during follow-up.

Leak was detected in only 1 of the patients with aneurysm rupture. In this patient, control CTA showed active extravasation extending to the abdomen and thorax at both ends of the graft. Four stent grafts were performed to manage leaks. Distal extravasation continued. It was thought that this leak was due to the incompatibility between the calcified atherosclerotic aortic wall and the stent. Additionally, simultaneous mid-stent leakage was observed. While the middle stent leak was effectively closed by placing two additional stent grafts at the leak sites, distal leak continued despite balloon dilatation. Percutaneous embolization was then closed for this area (Figure 2).

The least common complications were stent graft failure (3%) and bleeding (3%).

Acute renal failure was seen in three patients (9%). In one of these patients, a stent was placed for a type A dissection extending into the left renal artery. The other patient developed acute cerebral infarction and nosocomial infection and was lost during follow-up. The third patient was followed up with compensated renal failure.

Acute cerebral infarction (n=5, 15%) was most frequently seen in ruptured aortic aneurysms (n=3, 60%). One of these patients had acute renal failure and nosocomial infection mentioned above and was lost to follow-up.

Recurrence was detected on follow-up imaging in three patients (9%) (two with dissection and one with aneurysm). Among these two patients, one had type A dissection and the other had type A dissection, dissection in the superior mesenteric artery and bleeding in the jejunal artery branches. Surgery was performed for type A dissection. The recurrent aneurysm was treated with stent graft, and the other dissection was treated with microcoil embolization.



Figure 2. (a) Rupture of proximal and distal parts of the graft, (b) after procedure leakage (white arrow) and hematoma in thorax (black arrow) and abdomen (thick white arrow), (c) leakage (white arrow) and hematoma (black arrow), (d) leak continues after second EVSG
EVSG: Endovascular stent graft

Table 2. Risk factors of the diseases, coexisting diseases

	HT	DM	CAD	COPD	CRD	Cigarette smoking
Aneurysm	14	5	2	3	4	7
Dissection	13	2	5	1	1	3

HT: Hypertension, DM: Diabetes mellitus, CAD: Coronary artery disease, COPD: Chronic obstructive pulmonary disease, CRD: Chronic renal disease

Table 3. Complications in the patients who were performed stent graft procedure

	Descendan aort aneurysm (n=17)		Descendan aort dissection (n=17)	
	Non-ruptured (n=13)	Ruptured (n=4)	Acute (n=14)	Chronic (n=3)
Primer failure	-	1	-	-
Hemorrhage	-	-	1	-
Acut renal failure	-	1	1	1
Acut cerebral infarct	1	3	1	-
Nasocomial infection	1	2	1	-
Leakage	5	1	1	-
Additional stent necessity	1	1	2	2

Table 4. Stent-grafts used during the procedure and mortality rates

	Gore TAG	Medtronic Valiant/Captiva	Jotec E-VITA
Patient (n)	6	20	8
Mortality rates	17% (n=1)	10% (n=2)	0

In a patient treated for an aneurysm, a follow-up CTA scan performed one month after discharge revealed air and an abscess within the thrombosed aneurysmal wall. The patient had symptoms of fatigue, loss of appetite, cough and sputum production. The patient's infection was treated with appropriate antibiotic therapy (Figure 3).

A total of four patients, two with dissection, one with traumatic dissection, and one with a ruptured aneurysm, did not attend follow-up examinations and were therefore categorized as lost to follow-up.

The average hospital stay was 6 days in acute and chronic dissection cases, 4.2 days in aneurysm patients, and 14.6 days in traumatic dissections.

In the stent usage analysis, Medtronic VALIANT/CAPTIVA stents (29 devices) (n=20, 59%) were used the most. The mortality rate for these stents was 16.6% (1/6). There were no deaths among patients treated with E-VITA stents (Table 4).

Four patients were lost to follow-up after discharge, and no significant late complications were detected in the remaining patients.

The 30-day mortality rate of the patients was 8.82% (3/34) and the in-hospital mortality rate was calculated as 11.7% (4/34).

While the mortality rate in patients with ruptured aneurysms was 75% (3/4), this rate was 7% (1/14) in those with acute dissection. No mortality was observed in patients who underwent traumatic transection or chronic dissection.

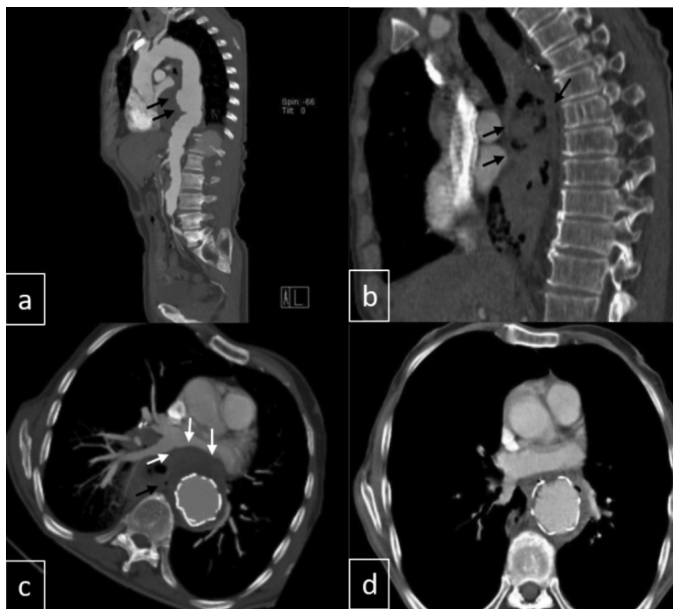


Figure 3. (a) Thrombosed aneurysm in the descending aorta (b), post-procedural air densities and abscess (c), air images (black arrow) in the right vicinity of stent graft and abscess (white arrow) (d), evident regression and decline in air images after treatment

Discussion

EVSG treatment in the thoracic aorta was first introduced in 1991 by Volodos et al.,¹⁸ with the first clinical series reported by Dake et al.¹⁹ in 1994 using Dacron-coated EVSG in 13 patients with descending aortic aneurysm, the first usage was reported by Bilgen et al.²⁰ in 2002 for thoracic aortic aneurysm (TAA) cases.

For aortic dissections, EVSG aims to close the intimal tear, promote thrombosis in the false lumen, improve flow in the true lumen, and restore perfusion to the aortic branches. In TAA, the aim is to reduce the aneurysmal tension by excluding the affected segment.

Pre-procedural evaluation with CT angiography is critical, as accessing the vascular system can be challenging in patients with underlying atherosclerosis.

As technology evolves, improvements in stent designs and more accurate indications have helped provide increasingly favorable data on mid- and long-term mortality outcomes following EVSG. Despite technological advances, data remain variable due to differences in stent choice and procedural indication. Elective surgical repair of aneurysms is known to effectively and permanently prevent rupture; however, mortality rates range from 5-22%.²¹ This rate increases in patients and those with comorbidities, including coronary artery disease, chronic renal failure, and chronic obstructive pulmonary disease. Mortality reaches approximately 50% in the presence of rupture,²² underscoring the need for early intervention in patients with advanced age or comorbidities.

Despite advancements in surgical techniques and postoperative care, urgent surgical intervention in acute Stanford type B dissection cases remains associated with high morbidity and mortality. In large published series, mortality rates in cases of acute traumatic rupture are 15-28%,²³ and for ruptured thoracic aneurysm resection, 50-60%.²⁴ Although endovascular procedures cannot revascularize intercostal arteries, some literature has reported spinal cord ischemia as a complication. In our study, paraplegia did not occur in any patient, but cerebral infarction developed in three cases (8.82% or 3/34) in the early phase. Due to early diagnosis and treatment, two of these cases had no residual effects, while one patient, who had a ruptured aneurysm, died in the second month due to concurrent acute renal failure and nosocomial infection. Recognizing early and late complications and implementing vigilant follow-up after EVSG are essential for timely diagnosis and appropriate intervention.

Because EVSG does not involve aortic clamping, patients generally maintain stable hemodynamics throughout the procedure.²⁵ Compared to surgery, EVSG often results in shorter hospital and intensive care unit stays, reducing complications such as nosocomial infections. In our study, the mean hospital stay was notably short, although traumatic transection patients required longer hospitalization due to associated traumatic injuries.

Complications can arise from both the procedure and the stent or graft itself, including aortic dissection, arterial perforation, distal embolization, pseudoaneurysm, infection, stent graft displacement,

collapse, endoleakage, and occlusion. Early-phase endoleakage rates are reported to range from 30-40%.²⁶ In our study, leakage occurred at a rate of 20.5% (7/34). All but one of the leaks were type 1 leaks. The type 2 leak seen in this patient during the follow-up examination resolved over time. While leakage continues to be a problem in EVSG, ongoing advances in stent technology, early detection and improved indications are attempting to alleviate this problem.

Among 10 patients treated for dissection, minimal false lumen filling was observed in the late phases of follow-up. Since this delayed filling reduces the direct transmission of systemic pressure to the false lumen and may inhibit aneurysm progression, these patients were observed without further intervention.²⁴

Additional and complementary surgical interventions are sometimes required following EVSG.¹⁸ In this series, two patients with type A dissection underwent EVSG after surgical graft interposition in the aortic arch and ascending aorta. The rate of post-procedural surgical intervention was 5.8% (2/34): one due to newly developing dissection in the aortic arch and ascending aorta, and the other due to left carotid-subclavian bypass surgery for closing the left subclavian artery.

Study Limitations

The first limitation of our study is its design and small sample size. The effectiveness, complexities, and limitations of EVSG should be validated by conducting larger-scale studies in the future. The second limitation is the short follow-up period of the patients. In this regard, tracking times can be extended to at least 5 years.

Conclusion

In conclusion, stent-graft placement is a safe, less invasive, and effective treatment for thoracic aortic aneurysms and fistulas and the complications of type B dissection. The major limitation of surgery is the presence of concomitant conditions, whereas the major limitation of stent-graft therapy is anatomic suitability. In selected patients, short-term morbidity and mortality from endovascular therapy compare favorably with those from surgery. Stent-graft therapy is currently the best option for a significant number of patients with descending thoracic aortic disease who are poor candidates for surgical repair.

Ethics

Ethics Committee Approval: Ethical approval for the study was granted by the Ethics Committee of Başkent University (code: KA 12-04, date: 16.02.2012).

Informed Consent: Because this was a retrospective study, informed consent was not required by the ethics committee.

Footnotes

Authorship Contributions

Surgical and Medical Practices: F.B., C.A., Concept: Ş.Y., F.B., C.A., Design: Ş.Y., C.A., Data Collection or Processing: Ş.Y., A.M.A., Analysis or Interpretation: Ş.Y., A.M.A., Literature Search: Ş.Y., A.M.A., Writing: Ş.Y.

Conflict of Interest: No conflict of interest was declared by the authors.

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