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Mid-Term Results of Using the Seal Thoracic Stent Graft in Cases of Aortopathy: A Single-Institution Experience

Jun Woo Cho, M.D., Jae Seok Jang, M.D., Chul Ho Lee, M.D., Sun Hyun Hwang, M.D.

Department of Cardiovascular and Thoracic Surgery, School of Medicine, Catholic University of Daegu, Daegu, Korea

Background: The endovascular approach to aortic disease treatment has been increasingly utilized in the past 2 decades. This study aimed to determine the long-term results of using the Seal thoracic stent graft. **Methods:** We retrospectively reviewed the outcomes of patients who underwent thoracic endovascular aortic repair or a hybrid procedure using the Seal thoracic stent graft (S&G Biotech, Seongnam, Korea) from January 2008 to July 2018 at a single institution. We investigated in-hospital mortality and the incidence of postoperative complications. We also investigated the mid-term survival rate and incidence of aorta-related complications. **Results:** Among 72 patients with stent grafts, 15 patients underwent the hybrid procedure and 21 underwent emergency surgery. The mean follow-up period was 37.86±30.73 months (range, 0–124 months). Five patients (6.9%) died within 30 days. Two patients developed cerebrovascular accidents. Spinal cord injury occurred in 2 patients. Postoperative renal failure, postoperative extracorporeal membrane oxygenation support, and pneumonia were reported in 3, 1, and 6 patients, respectively. Stent-related aortic complications were observed in 5 patients (6.8%). The 1- and 5-year survival and freedom from stent-induced aortic event rates were 81.5% and 58.7%, and 97.0% and 89.1%, respectively. **Conclusion:** The use of the Seal thoracic stent graft yielded good mid-term results. Further studies are needed to examine the long-term outcomes of this device.

Key words: 1. Thoracic aorta
2. Aortic rupture
3. Stents
4. Endoleak

Introduction

Since Dake et al. [1] first used stent grafts for treating thoracic aortic aneurysms in 1992, their use as the first-line treatment of descending thoracic aortic disease has been increasing [2]. Mid- and long-term results of thoracic endovascular aortic repair (TEVAR) have been reported in several studies, and the durability and stability of commercially available stent grafts are well characterized [3-13]. In Korea, stent grafts have been used for thoracic aortic disease for more than 10 years. Currently, the types of stent grafts used in Korea have become more diverse including those available on the North American or European markets, but the Seal thoracic stent graft (S&G Biotech, Seongnam, Korea) developed in Korea was the only type available for the treatment of thoracic aortic disease in Korea from 2007 to 2011, because foreign stent grafts could not be used due to restrictions in the Korean medical

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Corresponding author: Jae Seok Jang, Department of Cardiovascular and Thoracic Surgery, School of Medicine, Catholic University of Daegu, 33 Duryugongwon-ro 17-gil, Nam-gu, Daegu 42472, Korea
(Tel) 82-53-650-4566 (Fax) 82-53-629-6963 (E-mail) heartiscs@cu.ac.kr

market [14]. While it is still used at numerous centers in Korea, its long-term performance is unclear. Therefore, we investigated the mid- to long-term results of treating thoracic aortic disease using the Seal thoracic stent graft.

Methods

1) Patients

We studied 73 patients who received treatment for thoracic aortic disease with the Seal thoracic stent graft from January 2008 to July 2018 at Daegu Catholic University Medical Center. The thoracic aortic diseases included aortic dissection, intramural hematoma (IMH), aortic aneurysm, penetrating atherosclerotic ulcer (PAU), and aortic rupture. We included both patients with descending aortic disease and those who underwent a hybrid procedure for aortic arch disease. While hybrid procedures and TEVAR have been performed at our center since 2008 for aortic arch disease (except dissection), we have limited hybrid procedures to high-risk patients aged 75 years or older since 2015.

This study was performed after obtaining approval from the Institutional Review Board at Daegu Catholic University Medical Center (IRB approval no., CR-18-139-L), and the requirement for patient consent was waived due to the retrospective nature of the study.

2) Surgical considerations

An intervention was performed when the aneurysm size was greater than 55 mm or increased more than 5 mm per year. In addition, if the landing zone was favorable, TEVAR was performed; otherwise, a hybrid procedure was considered in elderly patients. In cases of aortic dissection, a stent graft was considered only in type B. In our center, TEVAR was performed in cases of complicated acute type B aortic dissection or subacute type B aortic dissection. In case of chronic type B aortic dissection, a limited operation was performed when surgery was considered high-risk. The classification of aortic dissection, including the definition of the complicated type, was determined based on the 2014 European Society of Cardiology guideline [2].

In cases of hybrid TEVAR, stent grafts were anchored in favorable landing zones. De-branched arch vessels were directly anastomosed to the aorta or grafted between arch vessels. Our approach to TEVAR has been described in a previously published study [15].

Table 1. Baseline patient profiles

Characteristic	Value
Demographic characteristics	
Age (yr)	64.40±15.51
Male sex	51 (70.8)
Height (m)	1.65±0.10
Weight (kg)	63.18±12.16
Past history	
Hypertension	39 (54.2)
Diabetes mellitus	9 (12.5)
Cerebrovascular accident	8 (11.1)
Malignancy	4 (5.6)
Current smoker	16 (22.2)
Chronic obstructive pulmonary disease	2 (2.8)
Liver cirrhosis	0
Hyperlipidemia	2 (2.8)
Myocardial infarction	0
Heart failure	3 (4.2)
Chronic kidney disease	1 (1.4)
Atrial fibrillation	2 (2.8)
Aortic pathology	
Dissection	25 (34.7)
Spontaneous	9
Traumatic	16
Intramural hematoma	7 (9.7)
Spontaneous	7
Traumatic	0
Aneurysm	33 (44.4)
Spontaneous	33
Traumatic	0
Penetrating atherosclerotic ulcer	2 (2.8)
Spontaneous	2
Traumatic	0
Rupture	6 (8.3)
Spontaneous	4
Traumatic	2

Values are presented as mean±standard deviation or number (%).

3) Data collection and study endpoint

Data were collected retrospectively from the medical records of patients who received computed tomography scans once a year with regular outpatient visits twice a year. Mortality was estimated in patients who were lost to follow-up through telephone

Table 2. Early operative outcomes

Complications	Overall	TEVAR alone	Hybrid TEVAR	p-value
30-Day mortality	5 (6.9)	3 (5.3)	2 (13.3)	0.277
Cerebrovascular accident	2 (2.8)	1 (1.8)	1 (6.7)	0.380
Spinal cord injury	2 (2.8)	1 (1.8)	1 (6.7)	0.380
Continuous renal replacement therapy	3 (4.2)	3 (5.3)	0	1.000
Reoperation for bleeding	1 (1.4)	1 (1.8)	0	1.000
Pneumonia	6 (8.3)	3 (5.3)	3 (20)	0.100
Postoperative extracorporeal membrane oxygenation	1 (1.4)	1 (1.8)	0	1.000

Values are presented as number (%).
TEVAR, thoracic endovascular aortic repair.

calls or by investigating whether they had lost their qualification for medical insurance.

The primary endpoint was 30-day mortality and postoperative neurological complications, including cerebrovascular accident (CVA) and spinal cord injury (SCI). CVA was defined as the presence of neurologic deficits with brain damage detected by computed tomography or magnetic resonance imaging, and SCI was defined clinically as paraplegia. In addition, patients' conditions were classified as transient if they recovered during the follow-up period and as permanent if they did not recover. Long-term survival, freedom from aortic events, and freedom from stent-induced aortic events were investigated as the secondary endpoints. Aortic events were defined as any additional intervention or surgery on the aorta during the follow-up period. Stent-induced aortic events were defined as endoleak or stent graft-induced new entry (SINE).

4) Statistical analysis

Continuous variables are expressed as mean±standard deviation, and categorical variables are expressed as frequency and percentage. The Mann-Whitney test was used for continuous variables and the chi-square test or Fisher exact test for categorical variables. Survival and aortic event–free periods were calculated using the Kaplan-Meier method and the log-rank test was used for comparisons between groups. All p-values <0.05 were considered to indicate statistical significance. All statistical analyses were performed using IBM SPSS software ver. 25.0 (IBM Corp., Armonk, NY, USA).

Results

During the study period, 72 consecutive patients underwent stent implantation, except for those who underwent a frozen elephant trunk procedure. The baseline characteristics of the patients are summarized in Table 1. Fifteen patients underwent hybrid TEVAR, and 21 underwent emergency surgery. The mean age of the patients was 64.40±15.51 years, and 70.8% were male. The mean follow-up period was 37.34±30.83 months (range, 0–124 months). The follow-up completion rate was 89.04%. There were 25 patients with aortic dissection, 7 with IMH, 32 with aneurysm, 2 with PAU, and 6 with aortic rupture. A total of 18 patients had traumatic aortic injury.

1) Operative profile

Preoperative cerebrospinal fluid drainage was performed in 66.7% of the 57 patients who underwent TEVAR alone, among whom the number of patients with coverage of zones 2, 3, and 4 was 11, 37, and 9, respectively. Eight of the 15 patients who underwent hybrid TEVAR underwent preoperative cerebrospinal fluid drainage. The number of patients with coverage of zones 0, 1, and 2 was 6, 5, and 4, respectively. The operation time was 111.40±66.60 minutes in patients undergoing TEVAR alone and 437.43±176.42 minutes in those undergoing hybrid TEVAR. There were no technical errors during any procedure, and the procedures were successful in all patients.

2) Early outcomes

Five patients (6.9%) died within 30 days, 4 of whom had undergone emergency surgery owing to a ruptured aorta. Two patients developed CVA, one of

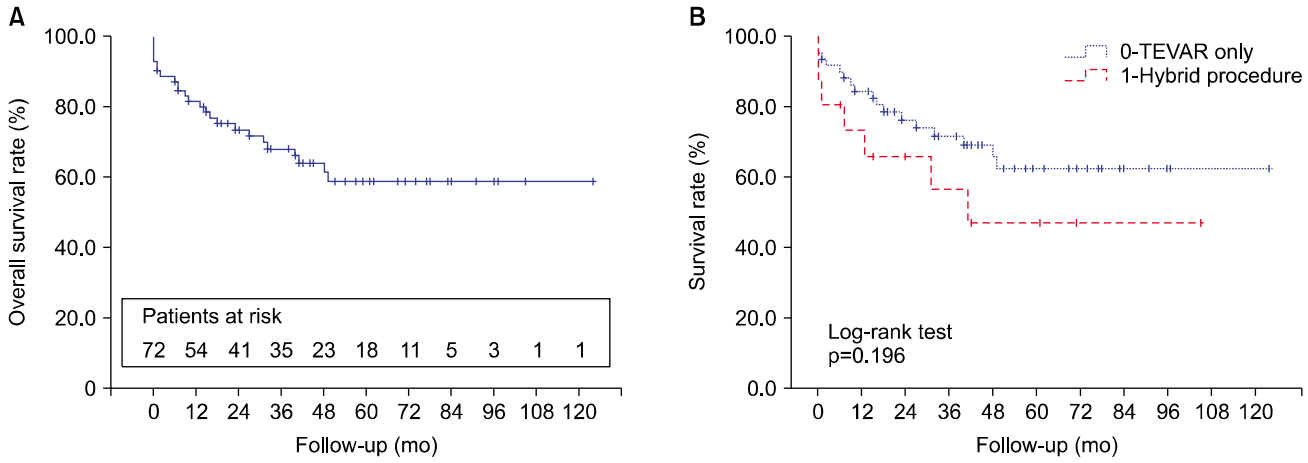

Fig. 1. Kaplan-Meier survival curves. (A) Overall survival. (B) Comparison of TEVAR and hybrid procedures. TEVAR, thoracic endovascular aortic repair.

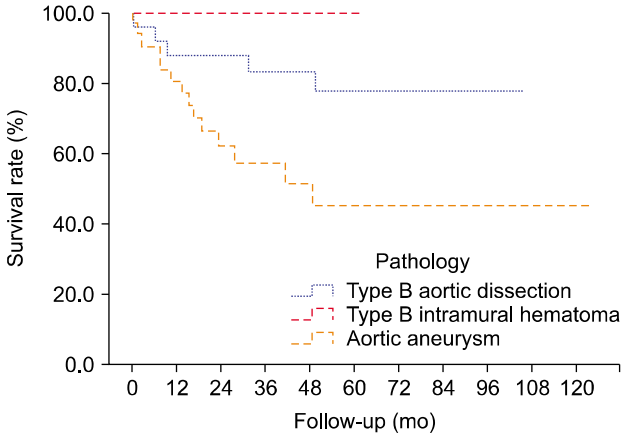

Fig. 2. Kaplan-Meier survival curve according to aortic pathology.

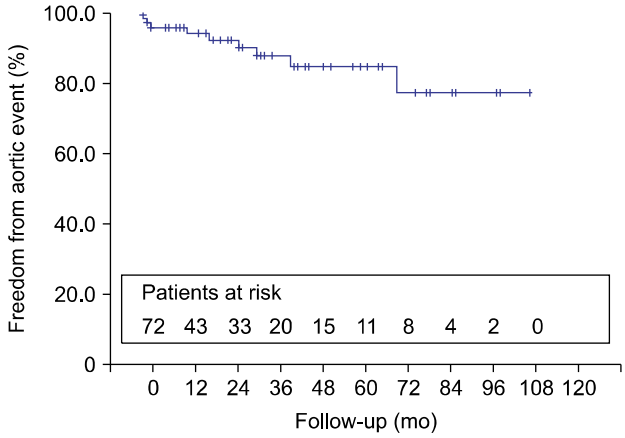

Fig. 3. Kaplan-Meier curve of overall freedom from aortic events.

whom underwent a hybrid procedure. SCI occurred in 2 patients, but 1 completely recovered during the hospitalization period. Postoperative renal failure, postoperative extracorporeal membrane oxygenation support, and pneumonia were reported in 4, 1, and 6 patients, respectively. There were no specific vascular complications, such as puncture site bleeding, thrombosis, or hematoma, after the procedures. Table 2 summarizes the complication rates according to the extent of surgery, showing no statistically significant difference.

3) Late outcomes

There were 19 late deaths due to cardiovascular causes (n=4), acute respiratory distress syndrome (n=3), sepsis due to infection (n=3), and cancer (n=5). The overall survival rate was 81.5%, 68.1%, and 58.7% at 1, 3, and 5 years, respectively. The survival curves for the TEVAR and hybrid procedure groups showed similar patterns, with no statistically significant difference (Fig. 1). When the survival rate was classified according to the aortic pathology, aneurysms had the most deleterious effect on long-term survival (Fig. 2). The overall rate of freedom from aortic events was 93.5%, 85.6%, and 81.7% at 1, 3, and 5 years, respectively (Fig. 3). Stent-related aortic complications were observed in 5 patients (6.8%): endoleak in 4 (type Ib in 3 and type III in 1), and SINE in 1. One patient with type III endoleak suffered from mycotic infection with an aortoesophageal fistula, and he underwent open surgery for descending thoracic aorta replacement. Endoleak

occurred in 2 patients with aneurysms and 2 with chronic type B aortic dissection, while SINE occurred in a patient with chronic type B aortic dissection. Among the patients with endoleak, 3 had undergone hybrid procedures. Except for the above cases, there were no stent-related aortic complications, such as stent fracture or migration (Table 3). The incidence of stent-induced aortic events in all patients, including those who underwent hybrid procedures, was 97.0% and 89.1% at 1 and 5 years, respectively, and 98.0% and 95.6% in those who underwent only TEVAR (Fig. 4). Comparing the survival and freedom from aortic event rates according to the occurrence of trauma revealed better survival in patients with traumatic aortic injuries. The 1- and 5-year survival rates of patients with traumatic aortic injuries (94.4% and 81.4%, respectively) and those without them (77.2% and 49.1%, respectively) were significantly different (p=0.031), but there was no statistically significant difference in freedom from aortic events. Similarly, no significant differences were observed when confining the analysis to patients who underwent TEVAR only. No stent-induced aortic events occurred in patients who underwent stent-graft implantation for traumatic aortic injuries.

Table 3. Late outcomes due to stent-related aortic complications

Complications	Overall
Endoleak	4 (5.5)
Stent graft-induced new entry	1 (1.4)
Infection	1 (1.4)
Fistula	1 (1.4)
Stent fracture	0
Migration	0

Values are presented as number (%).

Discussion

Stent graft implantation has become a cornerstone of aortic disease treatment. Our study investigated the mid- to long-term performance of stent grafts, which have been manufactured in Korea and used globally for a long period of time. Although no reliable data are available, numerous experienced aortic surgeons have doubted the strength of the Seal thoracic stent graft compared to other products and questioned its durability. In 2017, Song et al. [14] reported excellent results with the Seal thoracic stent graft, but no long-term data on outcomes are available.

The Seal thoracic stent graft is the only domestic graft, and compared to other foreign devices, it has smallest introducer (16F) [14]. Therefore, less invasive procedures can be performed, and luminal complications can be reduced. It can also be used in patients with a small iliac artery diameter. We considered that the occurrence of fewer vascular complications in our study was due to this advantage of a small introducer. In addition, since it is the only domestic product, it is considered advantageous that the device can be supplied in an individualized man-

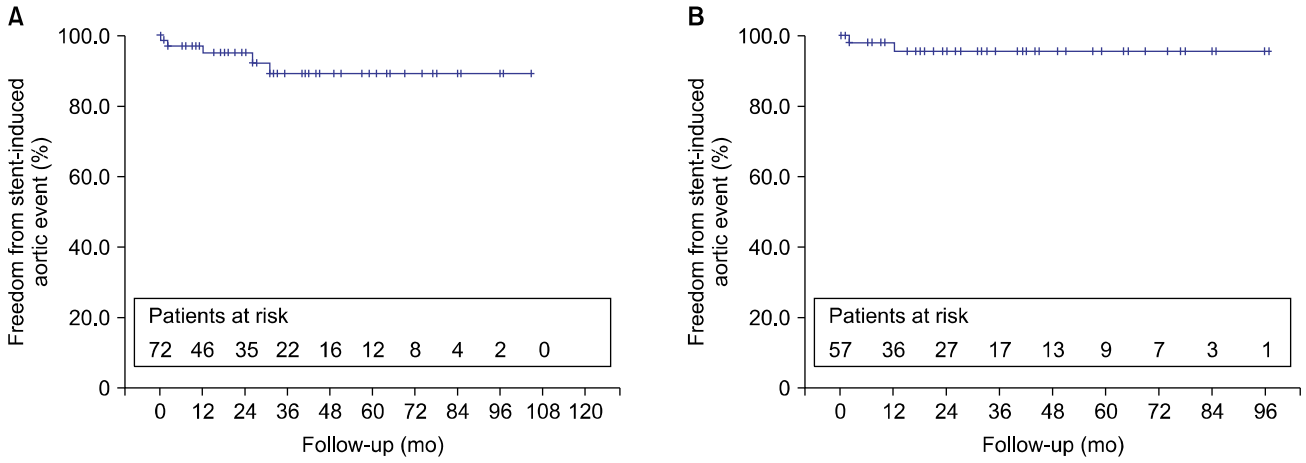

Fig. 4. Kaplan-Meier curves for freedom from stent-induced aortic events. (A) All patients, including those who underwent hybrid procedures. (B) Patients who underwent thoracic endovascular aortic repair only.

ner, according to patients' anatomical configurations. However, since it has not been in clinical use for a long time compared with foreign products, there are no known long-term results and a lack of related data. Therefore, although this study was conducted at a small-volume center, our research may be important in that it documents the longest postoperative outcomes of the Seal thoracic stent graft.

In this study, there was a concern regarding whether it should be conducted only among patients receiving TEVAR alone or those undergoing hybrid procedures as well. We concluded that it was reasonable to include patients who underwent hybrid procedures, since the aim of this study was to determine the clinical results associated with the Seal thoracic stent graft. Because of the different nature of the patient populations, we analyzed patients who underwent TEVAR alone separately.

The survival rate of patients with traumatic aortic injuries is well-known to be better than that of those with non-traumatic aortic disease [16-20]. We analyzed patients with traumatic aortic injuries separately and observed good results in terms of the survival and freedom from aortic event rates. However, a more-in depth analysis of trauma-related aortopathy should be conducted. Although there was no detailed analysis of the trauma-related issues in this study, it was clear that patients with traumatic aortic injuries were relatively young (48.72±16.64 versus 69.63±11.04 years, $p < 0.001$). We believe that a more detailed analysis could be conducted if the number of patients analyzed were to be increased.

Previous reports showed that the long-term survival rate of patients undergoing stent graft implantation was low [3-6]. In accordance with our results, most studies reported 5-year survival rates not exceeding 50%. However, the rates of long-term aortic complications associated with stent grafts is encouraging. Although Kaplan-Meier curve analysis may be inappropriate in our small study population, the 5-year outcome of freedom from stent-induced aortic events was excellent, at 89.1% in all patients and 95.6% in those who underwent only TEVAR. These good results do not exclude the possibility of a paradoxical outcome due to death before the occurrence of stent-related problems, since these patients with aortic disease generally have poor survival outcomes. We investigated causes of death in order to understand their impact. Across the entire cohort, late death from cardiovascular causes, including stent-related or aortic issues, was observed in only 2 patients. This indicates that stent-induced aortic events did not have a significant effect on patient mortality.

The limitations of our research are clear. First, the retrospective nature of the study is an unavoidable limitation. In addition, undetectable bias due to the lack of randomization is another limitation. Furthermore, the small study population made it difficult to analyze each aortic pathology in detail. As retrospective single-center data were analyzed, a prospective multi-center study will be needed to obtain results free from bias.

In conclusion, the Seal thoracic stent graft achieved good mid-term results. Although long-term follow-up was difficult owing to the low survival in these high-risk patients, the incidence of stent-related aortic complications was low. Further studies will be needed to examine the long-term outcomes of this device.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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ORCID

Jun Woo Cho: https://orcid.org/0000-0002-0786-9775
Jae Seok Jang: https://orcid.org/0000-0002-0693-8863
Chul Ho Lee: https://orcid.org/0000-0002-9139-0619
Sun Hyun Hwang: https://orcid.org/0000-0002-2461-9604

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