CLINICAL STUDY

Clinical Outcomes for Endovascular Repair of Thoracic Aortic Disease Using the Seal Thoracic Stent Graft: A Korean Multicenter Retrospective Study

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ABSTRACT

Purpose: To investigate the midterm outcomes of thoracic endovascular aneurysm repair (TEVAR) with the use of the Seal stent graft for four categories of thoracic aortic disease.

Materials and Methods: This retrospective multicenter study evaluated the records of 216 Korean patients who underwent TEVAR with the Seal stent graft during 2007–2010. The study outcomes were (*i*) perioperative death, (*ii*) endoleak, (*iii*) repeat intervention, (*iv*) aortic-related death, and (*v*) all sudden unexplained late deaths.

Results: The overall technical success rate was 94% (203 cases), and the disease-specific rates were 97% (88 cases) for aneurysms, 96% (71 cases) for dissections, 82% (32 cases) for traumatic aortic disease, and 100% (12 cases) for intramural hematoma and/or penetrating aortic ulcer. There were 6 acute surgical conversions (2 for aneurysms and 4 for dissections). There were 18 endoleaks, 4 retrograde ascending aortic dissections, and 6 stent graft–induced new entries. The 1-, 3-, and 5-year overall survival rates were 93% ± 3, 90% ± 4, and 90% ± 4, respectively.

Conclusions: TEVAR with the Seal thoracic stent graft provided a high technical success rate and low mortality and complication rates during midterm follow-up. However, additional long-term studies are needed to evaluate the durability and late complications associated with this device.

ABBREVIATIONS

IMH = intramural hematoma, PAU = penetrating aortic ulcer, rAAD = retrograde ascending aorta dissection, SINE = stent graft–induced new entry, TAD = traumatic aortic disease, TEVAR = thoracic endovascular aneurysm repair

Thoracic endovascular aneurysm repair (TEVAR) was introduced in 1992. Since then, several studies (1–4) have found that this technique provides better therapeutic results and lower mortality and morbidity rates than conventional open thoracic repair for lesions in the descending thoracic aorta. Although the safety and efficacy of TEVAR have been established for the treatment of thoracic aortic aneurysms and penetrating ulcers, a recent report of TEVAR for traumatic aortic transections and acute and chronic dissections (5) demonstrated favorable technical results and clinical outcomes.

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The Seal thoracic stent graft (S & G Biotech, Seongnam, Korea) has been available since 2007 and was the only available device for TEVAR from 2007 to 2011 in Korea. The device consists of a modular system that includes self-expanding nitinol-alloy stent rings, fully covered Dacron graft materials, strong radial force, and an 18-F preloaded introducer (6). Because stent grafts from other manufacturers were unavailable during this period in Korea, we questioned how many patients were effectively treated with this device during this period and whether there were any differences in treatment results compared with findings from other recent studies (1–4). This retrospective study aimed to evaluate the midterm outcomes of TEVAR with the use of this device.

MATERIALS AND METHODS

Patients

The institutional review boards of all participating hospitals approved the study design and waived the requirement for informed consent based on the study's retrospective design.

A total of 318 patients who underwent TEVAR with the Seal thoracic stent graft at 16 Korean university hospitals during the period of 2007–2010 were evaluated. The specific indications for TEVAR for localized lesions at the descending thoracic aorta included the following: (*i*) aneurysm $>$ 4.5 cm and rapid aneurysm growth of $>$ 5 mm/y, (*ii*) acute dissection $<$ 14 days with acute symptoms, (*iii*) acute disruption or transsection after trauma for traumatic aortic disease (TAD), and (*iv*) penetrating ulcer $>$ 10 mm and $\geq$ 20 mm in diameter for intramural hematoma (IMH) and/or penetrating aortic ulcer (PAU).

Forty-seven cases were excluded because of incomplete, unanalyzable clinical and procedural data, and 55 TEVAR cases were excluded because they involved lesions at the ascending aorta (40 type A dissections, seven type A aneurysms), abdominal aorta involvement (four thoracoabdominal aortic aneurysms), or no true aneurysm (four mycotic aneurysms). Therefore, 216 patients with lesions located between zone II and the distal descending thoracic aorta and with complete midterm follow-up data were included in the analysis. The patients' records contained baseline data regarding their demographic characteristics, comorbidities, American Society of Anesthesiologists physical status, anatomic characteristics of the target lesion, and details regarding the procedure (7).

The 216 patients included 156 men (72%) and had a mean age of 62 years ± 14 (median, 66 y; range, 19–89 y). The thoracic aortic diseases included true aneurysm (91 patients; 42%), type B dissection (74 patients; 34%), TAD (39 patients; 18%), and IMH and/or PAU (12 patients, 5%; n = 6 with IMH and PAU, n = 4 with PAU, and n = 2 with IMH). The patient demographics and clinical characteristics are presented in **Table 1**.

Procedure

The Seal thoracic stent graft includes two parts. The first part is a proximal 3-cm bare-metal stent that is knitted and wound using a single thread of nitinol wire. The bare-metal stent has a diameter as large as 40 mm and a noninterlocking diamond-shaped pattern, as well as six proximal barbs to provide better fixation to the aortic wall. These barbs have inward-facing tips to prevent direct injury to the aortic wall. The second part is a distal full Dacron graft (Texan, Daegu, Korea). This graft is 6–10 cm long, has a diameter as large as 36 mm, is tied to the bare-metal stent by 4–0 Prolene blue monofilament on a tapered needle, and has gold radiopaque V-markers at the proximal and distal ends of the graft (**Fig 1**). The 18–22-mm stent grafts were introduced by using a 16-F introducer, and 24–40-mm stent grafts were introduced by using an 18-F introducer, which provides a lower introducer profile compared with other commercially available devices.

The size of the stent graft was selected based on pre-TEVAR thoracic computed tomographic (CT) angiography, with oversizing of 10%–15% versus the diameter of the landing zone and 30–40 mm versus the length of the target lesion to ensure complete sealing of the landing zones (8). All procedures were performed by board-certificated interventional radiologists with $>$ 10 years of experience in aortic intervention.

Follow-up

After the primary TEVAR procedure, all patients underwent follow-up CT angiography at 1 month, 3 months, 6 months, 12 months, and then annually after their discharge. All patients were specifically assessed for decrease in the aneurysm sac or in the false lumen of the dissection, endoleak, retrograde ascending aorta dissection (rAAD), stent graft–induced new entry (SINE), and stent graft–related complications. Findings from the follow-up visits were retrospectively evaluated; these included clinical examination findings, CT angiography, magnetic resonance imaging, and/or echocardiography. Causes of death were determined based on death certificates, medical records, and autopsy reports (if available).

Definitions

The outcome reporting for the present study adhered to the guidelines from the ad hoc Committee for Standardized Reporting Practices in Vascular Surgery of the Society for Vascular Surgery/American Association for Vascular Surgery (9). In this context, technical success was related to periprocedural events that occurred between the initiation of the procedure and the first 24 hours after the procedure. Primary technical success was defined on an intent-to-treat basis and required the successful introduction and deployment of the device in the absence of surgical conversion, mortality, type I or