Original Article

Seven-Year Results of Endovascular Aneurysm Repairs of Abdominal Aortic Aneurysms with Custom-Made Stent Grafts

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Background: The purpose of this study was to determine the long-term results of a 7-year follow-up of endovascular aneurysm repairs (EVARs) of abdominal aortic aneurysms (AAAs) using custom-made stent grafts (SGs).

Methods and Results: We performed a retrospective review of 17 patients (14 males, 3 females; mean age: 74.3 ± 7.9 years; range: 53–85) undergoing EVAR of infrarenal aortic aneurysms at our institution from April 2000 to August 2006. The primary and secondary clinical success rates were 82.4% (14/17) and 100% (17/17). The initial and short-term clinical success rates were 100%. During follow-up (mean: 38.8 ± 35.9 months; range: 0.8–90 months), 4 patients died, but there was no aneurysm-related death. In 2 patients, additional surgery was performed. The long-term clinical success rate was 83.3% (5/6). In the Kaplan-Meier curve, the 1- and 5-year survival rates were 55.0% and 45.8%, respectively.

Conclusion: The initial and short-term clinical success rates were 100%; regarding the short-term, aneurysm-related death could be avoided. However, during long-term follow-up, aneurysm-related events did occur. Follow-up should be performed over a long period. (Ann Thorac Cardiovasc Surg 2010; 16: 26–30)

Key words: abdominal aortic aneurysm, endovascular aneurysm repair, custom-made stent graft

Introduction

In 1952, DuBost et al. performed artificial blood vessel replacement for abdominal aortic aneurysms (AAAs).[1] Since then, this procedure has been selected as a standard technique.[2] The incidence of graft failure has been 0.3%, and the long-term results have been stable.[3] Recently, however, the rapid aging of society has increased the number of high-risk patients with many risk factors; many issues have been raised concerning open surgery.[4] Based on this background, in 1991 Parodi et al. performed endovascular aneurysm repairs (EVARs) for AAAs.[5] Since then, EVAR has commonly been employed for AAAs in Europe and the United States. In Japan, clinical studies of a custom-made stent graft (SG) were also conducted during the latter half of the 1990s. Its usefulness and favorable initial results have been reported.[6] In our hospital since 2000, EVAR, using a custom-made SG, has been performed in patients in whom open surgery was considered too risky. We report the 7-year results.

Methods

We conducted a retrospective review of all consecutive patients undergoing EVAR of infrarenal aortic or aorto-iliac

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Received November 11, 2008; accepted for publication January 30, 2009

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Table 1. Patients' characteristics

	N = 17	%
Hypertension	10	58.8
Old cerebral infarction	3	17.6
Chronic heart failure	3	17.6
Hyperlipidemia	2	11.8
Previous cardiovascular surgery	2	11.8
Ischemic heart disease	2	11.8
Cancer	1	5.9
Chronic aortic dissection	1	5.9
Liver cirrhosis	1	5.9
Chronic obstructive pulmonary disease	1	5.9
More than 80 years old	5	29.4

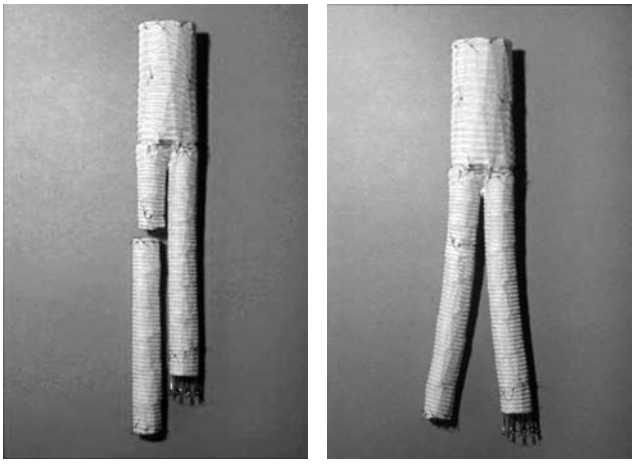

Fig. 1. The handmade SGs were constructed using Gianturco self-expandable stainless steel Z-stents (Cook Inc., Bloomington, IN, USA) covered with an ultrathin-wall woven polyester fabric (thickness 0.1 mm; Ube Industries Ltd., Yamaguchi, Japan).

artery aneurysms at our institution from April 2000 to August 2006. This study was approved by the Ethics Committee of the Nagasaki University School of Medicine, and written informed consent was obtained from all patients prior to endovascular repair.

Patients

The subjects were 17 patients who underwent EVAR using a custom-made SG from April 2000 to August 2006 (14 males, 3 females; mean age: 74.3 ± 7.9 years; range: 53–85 years). The mean follow-up period was 38.8 ± 35.9 months (range: 0.8–90 months).

Etiology

EVAR was performed in 17 patients: 15 with degenerative aneurysms (including 2 with rupture), 1 with a mycotic aneurysm caused by methicillin-resistant *Staphylococcus aureus* (MRSA), and 1 with an inflammatory aneurysm. Emergency EVAR was performed in 2 with rupture.

Patient characteristics

Ten patients had hypertension, 3 old cerebral infarction, 3 chronic heart failure, 2 hyperlipidemia, 2 angina pectoris, 1 terminal cancer, 1 chronic type B dissection, and 1 liver cirrhosis. Two patients underwent EVAR after open-heart surgery. One patient reported home oxygen therapy related to chronic occlusive pulmonary disease. Five patients were more than 80 years old (Table 1).

Patient selection

Our anatomical selection criteria for EVAR include the following:

1. The presence of a normal proximal aorta that is of sufficient length to allow implantation of the proximal aspect of the endovascular device. The recommended length is more than 1.5 cm.

2. The absence of severe angulation of the proximal neck. The recommended angulation between the suprarenal aorta and proximal neck is more than 60°.

3. The presence of iliac vessels with a sufficient caliber and limited tortuosity to allow passage of the introducer sheath.

4. The presence of iliac vessels with an adequate morphology for seating the distal portion of the SG, if the site selected for distal implantation is the iliac artery.

5. The absence of aberrant vessels, especially indispensable accessory renal arteries, in the segment of the aorta to be excluded from circulation.

Procedure

EVAR was performed in the angiography suite under general anesthesia in all but one procedure. The remaining procedure was performed under local anesthesia. EVAR was conducted using a custom-made SG composed of a Gianturco self-expandable stainless steel Z-stent (Cook Inc., Bloomington, IN, USA) and an ultrathin-wall woven polyester fabric (thickness: 0.1 mm; Ube Industries Ltd., Yamaguchi, Japan) (Fig. 1). A total of 5,000 U heparin was administered at the beginning of the procedure. After femoral arteriotomy, the SG was introduced through a 20 or 22 Fr. introducer sheath (a Keller-Timmermans introducer set, Cook, U.S., or a Medikit introducer set, Medikit, Tokyo, Japan). Initially, the tip of the SG delivery sheath was positioned slightly beyond the lesion, and

the SG was pushed up to the distal extremity of the delivery system. Once the SG had been positioned correctly, the sheath was gently retracted over the pusher and the SG freely expanded, adhering to the aorta. If the attachment to the aorta was insufficient, a balloon catheter was used to expand the SG, thereby ensuring good contact with the vessel wall at both ends. In all cases, the SG was placed to cover the lesion and at least 1.5–2.0 cm of the normal aorta, proximal and distal to the lesion. In cases of an aorto-unilateral SG, coil embolization of the contralateral common iliac artery and a femorofemoral crossover bypass procedure were subsequently performed.

Statistical Analysis

The data are expressed as the mean ± standard deviation. Kaplan-Meier analysis was employed to evaluate survival and aneurysm-related events (such as endoleak and migration).

Results

Initial results

Techniques consisted of tube graft in 7 patients, bifurcated graft in 8, and unigraft and femorofemoral bypass in 2. Chaikof et al. described that clinical success should be reported on an insert-to-treat basis. Further, it requires successful deployment of the endovascular device at the intended location without death as a result of aneurysm-related treatment, type 1 or 3 endoleak, graft infection or thrombosis, aneurysm expansion, aneurysm rupture, or conversion to open repair.[7] Clinical failure includes failure to deploy the endovascular device at the intended location, the presence of a type 1 or 3 endoleak, graft infection or infection, aneurysm expansion, aneurysm rupture, conversion to open repair, or death as a result of aneurysm rupture or aneurysm-related treatment. Initial clinical success encompasses 30-day data. Short-term clinical success includes outcome measures reported within a 30-day to 6-month time frame. Midterm clinical success refers to all outcome measures that are statistically significant up to 5 years after endograft implantation. Long-term clinical success includes all outcome measures that are statistically significant beyond 5 years. Primary clinical success is obtained with the use of an additional or secondary surgical procedure. Secondary clinical success is clinical success without the need for an additional or secondary surgical or endovascular procedure.

Overall, the primary clinical success rate was 82.4% (14/17), and the secondary clinical success rate was 100% (17/17) (Table 2). One 85-year-old male had a Fitzgerald type I ruptured AAA. Underlying diseases included chronic heart failure, hemiplegia following old cerebral infarction, liver cirrhosis, and chronic occlusive pulmonary disease. Home oxygen therapy had been used. Open surgery was considered too risky, and emergency EVAR (unigraft + femorofemoral bypass) was performed under local anesthesia. EVAR was successful, but the patient died of heart failure after 25 days. This is not an EVAR-related death, so the initial clinical success rate was 100% (16/16).

Table 2. Primary and secondary clinical success

	N = 17	%
Primary clinical success	14	82.4
Secondary clinical success	17	100
Clinical failure	3	17.6

Short-term results

During follow-up, 2 patients died, but they were not EVAR-related deaths. One, a 55-year-old male, had been admitted for the treatment of terminal laryngeal cancer. Emergency EVAR (tube graft) for a mycotic aneurysm caused by methicillin-resistant *Staphylococcus aureus* (MRSA) was performed, but after 40 days, the patient died of cancer. Another, an 82-year-old female, had an underlying disease of chronic heart failure. EVAR (tube graft) for an AAA was performed, but she died of pneumonia after 43 days. The short-term clinical success rate was 100% (14/14).

Midterm results

Aneurysm-related events were observed in 2 of the 14 patients (14.2%), and they were switched to open surgery;. In one 71-year-old female, EVAR with a tube graft was performed, but CT revealed type 1 endoleak after 19 months; therefore open surgery was performed. In the other, a 72-year-old male, EVAR with a bifurcated graft was performed, but flexion of the SG conjugation site was noted after 34 months, and open surgery was performed. During follow-up, 4 patients died; the causes of death consisted of heart failure in 1 patient, fatal arrhythmia in 1, and acute subdural hematoma in 2, but the deaths were not EVAR related. The midterm clinical success rate was 57.1% (8/14).

Long-term results

The long-term clinical success rate was 83.3% (5/6). One patient showed an increase in the aneurysmal diameter

Table 3. Long-term clinical success

		%
Initial clinical success	16/16	100
Short-term clinical success	14/14	100
Midterm clinical success	8/14	57.1
Long-term clinical success	5/6	83.3
Open conversion	2	11.8

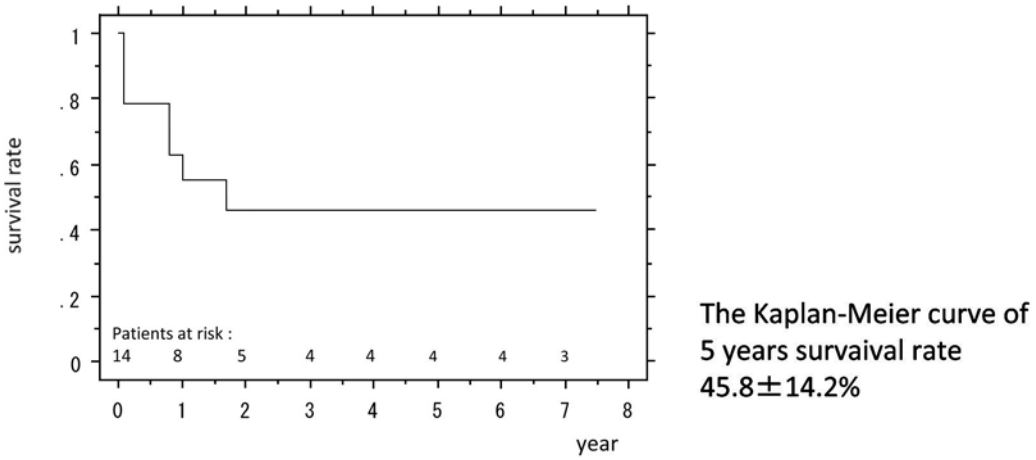

Fig. 2. Survival rate.

(64 mm) related to the flexion of the stent conjugation site. The patient did not wish to undergo additional surgery, and follow-up is being continued. In the Kaplan-Meier curve, the 1- and 5-year survival rates were 55.0% and 45.8%, respectively (Table 3, Fig. 2).

Discussion

The mortality rate related to open surgery for AAAs is approximately 2.7%, and the long-term results are stable. However, this technique is very invasive. Many studies, including the EVAR trial 1[8] and the Dutch Randomized Endovascular Aneurysm Management (DREAM) trial,[9] reported that EVAR decreased the surgery-related mortality rate in comparison with open surgery. They also reported that it shortened the admission period and interval until recovery, and its initial results exceeded those of conventional surgical procedures.[10] The results of EVAR using a custom-made SG in our hospital were favorable; the initial and short-term clinical success rates were 100%, and the long-term clinical success rate was 83.3%.

Concerning the limitations of EVAR, devices and surgical procedures remain under development, and long-term results have not been sufficiently reviewed, nor has the safety and accuracy of this treatment been demonstrated. Therefore CT should be performed over a long period after EVAR. In the EVAR trial 1, the 4-year survival rate was significantly higher in the EVAR group. However, the incidence of postoperative complications in this group after 4 years was 41%, indicating that complications during follow-up must be considered.[8] Many studies reported that complications during mid- and long-term follow-up required treatment, although the initial results of EVAR using a custom-made SG were stable.[11–15] In our hospital, we encountered aneurysm-related events in 3 patients: 1 after tube grafting and 2 after bifurcated grafting. Faries et al. indicated that tube grafting made peripheral implantation difficult in some cases, leading to events such as endoleak and migration.[16] Furthermore, the custom-made SG used had no barb on the central side. For this reason it may not have resisted aortic pressure, resulting in migration during long-term follow-up, thus causing events.[17] Commercial-type SGs have barbs, which may improve mid- and long-term results. Therefore we now use commercial-type SGs as our first choice.

In the American College of Cardiology and American

Heart Association guidelines in 2005, it is recommended that class IIa EVAR should be performed in patients with a poor general condition in whom open surgery is considered to be difficult, and that class IIb EVAR should be performed in low-risk patients. Concerning the pathological examination of aneurysms after EVAR, several studies reported that aortic aneurysmal thrombi showed no organization, and that there was no strong adhesion between an SG and the aortic wall or aneurysmal thrombus, leading to migration, aneurysmal infection, and type 1 endoleak via SG instability under arterial pressure.[18,19)]

Dillavou et al. indicated that EVAR should be selected as a first-choice treatment for AAAs in comparison with open surgery.[19)] After EVAR, however, close long-term follow-up by CT is needed;[10)] therefore in patients in whom long-term follow-up is impossible and those in whom open surgery can be safely performed, surgery should be carried out initially.

Conclusion

EVAR using a custom-made SG could be safely performed even in high-risk patients. The initial and short-term clinical success was favorable. However, aneurysm-related events were noted during long-term follow-up, and close follow-up is necessary.

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