Original Article

Morphological Study of Abdominal Aortic Aneurysm: Optimal Stent-graft Size for Japanese Patients

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Purpose: We report on the optimal stent-graft (SG) size for Japanese patients with abdominal aortic aneurysm (AAA).

Materials and Methods: Ninety three Japanese patients undergoing elective AAA repair were selected for this study. The parameters measured were the proximal neck (PN) diameter (D1), the diameter of the right and left common iliac arteries (D2 and D3, respectively), the diameter of the right and left external iliac arteries (D4 and D5, respectively), the distance between the lowest renal artery and the common iliac arterial bifurcation (L1), and the distance between the right and left common iliac arterial bifurcations and the internal iliac arterial bifurcation (L2 and L3, respectively).

Results: The following results were obtained: D1: 20.7±3.9 mm (14 to 28 mm); D2: 14.0±3.0 mm (9.5 to 20 mm); D3: 13.8±3.1 mm (9 to 19.5 mm); D4: 7.5±1.0 mm (6 to 10 mm); D5: 7.4±0.9 mm (6 to 10 mm); L1: 107.7±13.4 mm (80 to 130 mm); L2: 40.0±10.1 mm (20 to 61 mm); L3: 39.7±9.6 mm (20 to 60 mm).

Conclusion: The results indicate the necessity of exercising adequate care when selecting a device for Japanese patients. (Ann Thorac Cardiovasc Surg 2006; 12: 121–5)

Key words: abdominal aortic aneurysm, morphological study, Japanese, endoluminal grafting, stent-graft

Introduction

Following the commercial launch of various devices for endoluminal grafting (EG), EG is swiftly becoming an accepted procedure for the treatment of abdominal aortic aneurysm (AAA) in Western countries.[1-11] In the United States, five devices for EG have been approved by the Food and Drug Administration (FDA): the AneuRx® device (Medtronic Inc., Santa Rosa, CA, USA), Ancure® device (Guidant Cardiac and Vascular Division, Menlo Park, CA, USA), Excluder® device (W.L. Gore & Associates Inc., Flagstaff, AZ, USA), Zenith® device (Cook Inc., Brisbane, Australia), and PowerLink® device (Endologix, Inc., Irvine, CA, USA). In Japan, clinical trials have been completed for only two devices,[12,13] and neither has been approved for clinical use yet. The percentage of AAA patients who are suitable candidates for EG reported from Western countries varies widely among reports, ranging from below 10% to over 80%.[14-21] As few reports have been published in Japan concerning the suitability of EG in AAA patients,[13] it still remains to be determined what percentage of patients with AAA in Japan might be suitable candidates for EG. In order for EG to become established as a standard therapy for AAA, it is essential for surgeons to become familiar with the morphological features of AAA in Japanese patients and to select optimal devices for individual patients. In this paper, we report the results of a morphological analysis of AAA patients conducted at our center.

Materials and Methods

During the period from July 1993 to May 2005, 194 pa-

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Table 1. Clinical and aortoiliac morphological characteristics of abdominal aortic aneurysm (AAA) patients

Clinical	
Mean age	71 (55~88)
Men/women	81/12
Max. diameter (mm)	55 (40~80)
Procedures	
Open repair	72
Endoluminal repair	21
Morphological	
D1 (mm)	20.7±3.9 (14~28)
D2	14.0±3.0 (9.5~20)
D3	13.8±3.1 (9~19.5)
D4	7.5±1.0 (6~10)
D5	7.4±0.9 (6~10)
L1	107.7±13.4 (80~130)
L2	40.0±10.1 (20~61)
L3	39.7±9.6 (20~60)

D1, proximal neck diameter; D2, diameter of right common iliac artery; D3, diameter of left common iliac artery; D4, diameter of right external iliac artery; D5, diameter of left external iliac artery; L1, distance from lowest renal artery to aortic bifurcation; L2, length of right common iliac artery; L3, length of left common iliac artery.

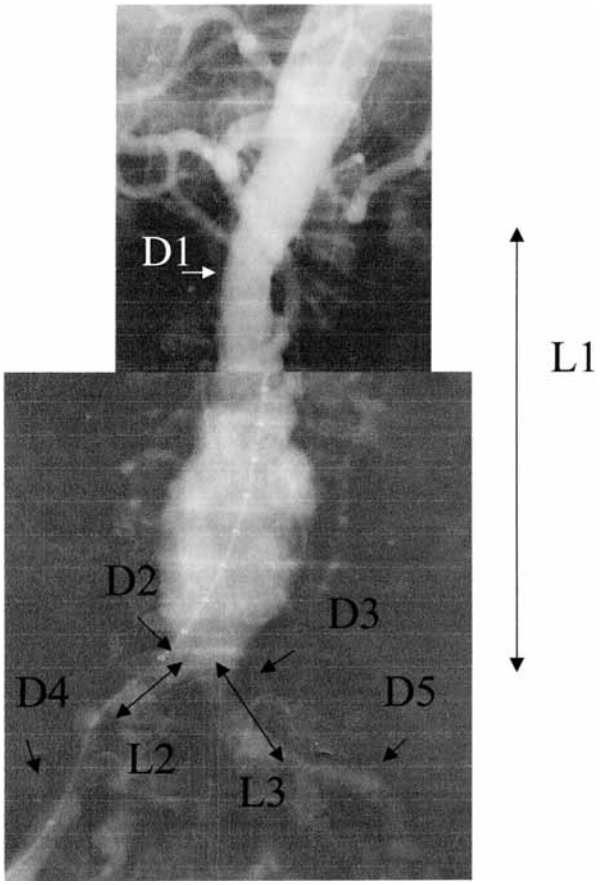

Fig. 1. Measurement of abdominal aortic aneurysm (AAA) dimensions.
D1, proximal neck diameter; D2, diameter of right common iliac artery; D3, diameter of left common iliac artery; D4, diameter of right external iliac artery; D5, diameter of left external iliac artery; L1, distance from lowest renal artery to aortic bifurcation; L2, length of right common iliac artery; L3, length of left common iliac artery.

tients with uncomplicated infrarenal AAA, excluding isolated iliac arterial aneurysm, underwent elective surgery at our center. Of these, 93 patients not fitting any of the following exclusion criteria were selected for this study: (1) proximal neck (PN) length of 15 mm or less, (2) neck angulation of 60 degrees or more, (3) difficulty in preservation of the internal iliac artery, and (4) difficulty in insertion of a device. These four exclusion criteria were used because most devices currently available in the market are not suitable for patients fitting any of these criteria.[1-13] Of the 93 patients (81 men; mean age 71 years, range 55 to 88) enrolled in the study. Maximum aneurysm size was 40 to 80 mm (mean: 55 mm). The operative procedure was open repair in 72 cases and EG in 21 cases (Table 1).

For patients studied before 1998, spiral CT (3- to 5-mm slices) and angiography using a catheter with a marker were employed for measurements. After 1999, 3-dimensional high-function CT images (3-mm slices) were used for measurements in all patients. Measurements were conducted by 2 cardiovascular surgeons who had performed EG as the main surgeon or the first assistant in 10 or more cases.

The parameters measured were the PN diameter (D1), the diameter of the right and left common iliac arteries (D2 and D3, respectively), the diameter of the right and left external iliac arteries (D4 and D5, respectively), the distance from the lowest renal artery to the bifurcation of the common iliac artery (L1) and the distance from the right and left common iliac arterial bifurcations to the internal iliac arterial bifurcation (L2 and L3, respectively) (Fig. 1). The values of these parameters measured in our patients were compared with published data for Western patients.

The eligibility of and potential concerns referable to 4 current stent-graft (SG) devices (AneuRx®, Excluder®, Zenith®, and PowerLink®) were evaluated. Exclusion criteria were as follows; 1) mismatch between D1 and proximal diameter of SG, 2) mismatch between D2 or D3 and

Table 2. Comparison of aortoiliac morphological characteristics of several papers

Authors/ref. no.	D1 (mm)	D2 (mm)	D3 (mm)	D4 (mm)	D5 (mm)	L1 (mm)	L2 (mm)	L3 (mm)
Resch T et al.[1)]	23.0±3.5	17.0±7.0	17.0±8.0			120.0±13.0	49.0±15.0	51.0±14.0
Alric P et al.[22)]	25.5±2.9	18.7±9.2	16.7±6.6			125.4±30.9	53.2±17.4	52.4±16.6
Matsumura JS et al.[7)]	22.3±0.14	12.4±0.19	11.8±0.15					
Criado FJ et al.[10)]	24.4±13.0	14.7±5.1	14.1±4.2					
Carpenter JP et al.[23)]	23.5±2.8	12.3±2.3	12.0±1.8			113.0±17.1	49.1±39.5	45.5±19.0
Arko FR et al.[21)]	22.6±0.2	14.0±0.4	13.4±0.2	9.6±0.1	9.4±0.1	108.8±1.2		
Cheng SW et al.[24)]	23.3±3.6	20.2±8.7	17.9±8.6			116.9±13.0	29.9±13.1	34.2±13.7
Current study	20.7±3.9	14.0±3.0	13.8±3.1	7.5±1.0	7.4±0.9	107.7±13.4	40.0±10.1	39.7±9.6

D1, proximal neck diameter; D2, diameter of right common iliac artery; D3, diameter of left common iliac artery; D4, diameter of right external iliac artery; D5, diameter of left external iliac artery; L1, distance from lowest renal artery to aortic bifurcation; L2, length of right common iliac artery; L3, length of left common iliac artery.

Table 3. Device specifications

Devices	Main body		Iliac leg(s)	
	Length (cm)	Diameter (mm)	Length (cm)	Diameter (mm)
AneuRx®	13.5, 16.5	20, 22, 24, 26, 28	8.5, 11.5	12, 13, 14, 15, 16
Excluder®	14, 16, 18	23, 26, 28.5, 31	10, 12, 14	12, 14.5, 16, 18, 20
Zenith®	7.4, 8.8, 10.3, 11.7, 13.2	22, 24, 26, 28, 30, 32	3.7, 5.4, 7.1, 8.8, 10.5, 12.2	8, 10, 12, 14, 16, 18, 20, 22, 24
PowerLink®	8, 10	25, 28, 34	4, 5.5	16

Table 4. Primary reasons for endovascular repair ineligibility

Devices	Small D1	Small D2 or D3	Large D2 or D3	Short L1+L2 or L3
AneuRx®	10 cases (11%)	–	11 (12)	31 (33)
Excluder®	25 (27)	–	–	31 (33)
Zenith®	22 (24)	–	–	–
PowerLink®	42 (45)	20 (22)	11 (12)	–

D1, proximal neck diameter; D2, diameter of right common iliac artery; D3, diameter of left common iliac artery; L1, distance from lowest renal artery to aortic bifurcation; L2, length of right common iliac artery; L3, length of left common iliac artery.

the distal diameter of SG (the distal landing zone has to be at either common iliac artery), 3) L1+L2 or L3 is shorter than the total length of devices (the distal landing zone has to be at either common iliac artery).

Results

The results of the measurements were as follows, as shown in Table 1: D1: 20.7±3.9 mm (14 to 28 mm); D2: 14.0±3.0 mm (9.5 to 20 mm); D3: 13.8±3.1 mm (9 to 19.5 mm); D4: 7.5±1.0 mm (6 to 10 mm); D5: 7.4±0.9 mm (6 to 10 mm); L1: 107.7±13.4 mm (80 to 130 mm); L2: 40.0±10.1 mm (20 to 61 mm); L3: 39.7±9.6 mm (20 to 60 mm). When compared with the data reported from previous morphological studies of AAA, primarily conducted in Western countries,[1,7,10,21-24)] while the values of D2, D3, and D4 showed no discernible trend, those of D1, L1, L2 and L3 tended to be smaller and shorter in our patients as compared to those reported for patients in Western countries (Table 2).

Table 3 presents the device specifications.[6,8,9,11)] The primary reasons for endovascular repair ineligibility by the AneuRx® device were small D1 (11%), large D2 or D3 (12%), and short L1+L2 or L3 (33%). The reasons by the Excluder® device were small D1 (27%) and short L1+L2 or L3 (33%). The reasons by the PowerLink® device were small D1 (45%), small D2 or D3 (22%), and large D2 or D3 (12%). The only reason by the Zenith® device was small D1 (24%); this device appeared to be the most suitable graft for our Japanese patients (Table 4).

Discussion

For cases of AAA, EG has been reported to yield better short-term results than conventional open repair, being associated with reduced blood loss, operative time, volume of blood transfusion required during surgery, length of stay in the ICU, and postoperative hospital stay, with reported long-term results following EG comparable to or better than those reported after open repair.[2,7] Such data establishes EG as an important, viable alternative to open repair when selecting a surgical procedure for the treatment of AAA.

However, the percentage of suitable candidates for EG among all patients with AAA varies greatly among reports, ranging from below 10% to over 80%.[14-21] There is no widely accepted view as regards the percentage of AAA patients indicated for this procedure. One reason for the wide variation in suitability statistics is that judgment of the suitability of patients for this procedure depends upon the specific device to be employed as well as anatomical differences among individual patients.

Moore et al.[14] reported that only 15% of AAA patients were suitable candidates for procedures involving use of the first-generation EG devices. On the other hand, other investigators have reported that the procedure involving aorto-uniiliac SG and femoro-femoral crossover bypass is suitable for more than 80% of patients with AAA.[17] Several studies comparing the specificity of different devices have also been published in recent years.[25,26] Ouriel et al.[25] evaluated the short-term and long-term outcomes of treatments employing five separate EG devices (Ancure®, AneuRx®, Excluder®, Talent, and Zenith®), and reported that the Ancure device often led to limb occlusion, the Excluder® often led to endoleak, and the Zenith® often resulted in modular separation, despite yielding a higher aneurysm reduction rate. AbuRahma[26] compared the outcomes of EG using three different devices (Ancure®, AneuRx®, and Excluder®), and reported that perioperative complications and initial technical failures were more likely to occur following the use of the Ancure® device. In Japan, no device for EG has yet been approved by the regulatory authority (Ministry of Health, Labour and Welfare), and it remains to be ascertained whether the devices designed for Western patients can be directly applied to Japanese patients, who on average differ in physique from Western patients. Studying the morphological features of AAA among Japanese patients and exploring how these features differ from Western patients will contribute to promotion of the application of EG to Japanese patients in the future.

The results of the present study indicate that the diameter of PN is smaller in Japanese patients as compared to that reported for Western patients, and that the distance between the renal artery and common iliac arterial bifurcation and the distance between the common iliac arterial bifurcation and internal iliac arterial bifurcation tended to be shorter in Japanese patients as compared to the values reported for Western patients. Cheng et al.[24] also conducted a morphological study of AAA among Asian patients and reported that the distance between the renal artery and common iliac artery bifurcation and the distance between the common iliac artery bifurcation and internal iliac artery bifurcation tended to be shorter in Asian patients as compared to the corresponding values reported for Western patients, consistent with the results of our study. In view of these findings, we may conclude that a device suitable for Japanese patients would need to offer extensive variations in PN diameter and total length. Related to this, Cheng et al.[24] reported that the need for an accurate landing in a short common iliac artery and insufficient length for maneuvering placed constraints on 2-piece graft designs with long main body lengths. For those reasons, he suggested that a 3-piece endograft (Zenith® device) with wider aortic and iliac diameters is currently the most attractive option for Asian patients. Our results lead us to the same conclusion.

Unlike the present study, in which all the patients with AAA at a given facility were evaluated (excluding those fitting the exclusion criteria for EG), most of the previously reported morphological studies of AAA involved only patients who underwent EG and did not include patients who underwent open repair or other treatment. The data in those reports may therefore involve some biases. From this point, the next desirable step is for morphological studies of AAA patients to be conducted at additional facilities in Japan, with the data from such studies utilized for the development and improvement of EG devices, with the ultimate goal of promoting their clinical use in Japan.

Conclusion

The diameter of the PN tended to be smaller, and the distances between the renal artery and common iliac arterial bifurcation and between the common iliac arterial bifurcation and internal iliac arterial bifurcation shorter, in Japanese patients than the values reported for Western patients. On the basis of these results, we may conclude

that only SGs offering extensive variations in PN diameter and total length would be suitable for Japanese patients.

References

1. Resch T, Malina M, Lindblad B, Ivancev K. The impact of stent-graft development on outcome of AAA repair—a 7-year experience. *Eur J Vasc Endovasc Surg* 2001; **22**: 57–61.
2. Arko FR, Hill BB, Olcott C, Harris EJ Jr, Fogarty TJ, Zarins CK. Endovascular repair reduces early and late morbidity compared to open surgery for abdominal aortic aneurysm. *J Endovasc Ther* 2002; **9**: 711–8.
3. Elkouri S, Martelli E, Gloviczki P, et al. Most patients with abdominal aortic aneurysm are not suitable for endovascular repair using currently approved bifurcated stent-grafts. *J Endovasc Ther* 2003; **10** (Suppl): I-16.
4. Hansen CJ, Aziz I, Kim BB, Donayre CE, White RA, Endologix Investigators. Results from the Endologix PowerLink multicenter trial. *Semin Vasc Surg* 2003; **16**: 166–70.
5. Haulon S, Devos P, Willoteaux S, et al. Risk factors of early and late complications in patients undergoing endovascular aneurysm repair. *Eur J Vasc Endovasc Surg* 2003; **25**: 118–24.
6. Carpenter JP, Endologix Investigators. Multicenter trial of the PowerLink bifurcated system for endovascular aortic aneurysm repair. *J Vasc Surg* 2002; **36**: 1129–37.
7. Matsumura JS, Brewster DC, Makaroun MS, Naftel DC. A multicenter controlled clinical trial of open versus endovascular treatment of abdominal aortic aneurysm. *J Vasc Surg* 2003; **37**: 262–71.
8. Bush RL, Najibi S, Lin PH, et al. Early experience with the bifurcated Excluder endoprosthesis for treatment of the abdominal aortic aneurysm. *J Vasc Surg* 2001; **34**: 497–502.
9. Sternbergh WC 3rd, Money SR, Greenberg RK, Chuter TA, Zenith Investigators. Influence of endograft oversizing on device migration, endoleak, aneurysm shrinkage, and aortic neck dilation: results from the Zenith Multicenter Trial. *J Vasc Surg* 2004; **39**: 20–6.
10. Criado FJ, Fairman RM, Becker GJ, Talent LPS Pivotal Clinical Trial Investigators. Talent LPS AAA stent graft: results of a pivotal clinical trial. *J Vasc Surg* 2003; **37**: 709–15.
11. Ayerdi J, McLafferty RB, Markwell SJ, et al. Indications and outcomes of AneuRx Phase III trial versus use of commercial AneuRx stent graft. *J Vasc Surg* 2003; **37**: 739–43.
12. Ishimaru S, Kawaguchi S, Hoshino S, et al. Bifurcated endovascular graft for abdominal aortic aneurysm repair: a multi-center trial of the PowerWeb™ system. *Jpn J Cardiovasc Surg* 2004; **33**: 81–6.
13. Midorikawa H, Ogawa T, Satou K, Hoshino S. How many patients with abdominal aortic aneurysm are suitable for endovascular repair using an Endologix PowerWeb system (EPW)? *Jpn J Vasc Surg* 2004; **13**: 579–83.
14. Moore WS, Rutherford RB. Transfemoral endovascular repair of abdominal aortic aneurysm: results of the North American EVT phase 1 trial. EVT Investigators. *J Vasc Surg* 1996; **23**: 543–53.
15. Moritz JD, Rotermund S, Keating DP, Oestmann JW. Infrarenal abdominal aortic aneurysms: implications of CT evaluation of size and configuration for placement of endovascular aortic grafts. *Radiology* 1996; **198**: 463–6.
16. Bayle O, Branchereau A, Rosset E, et al. Morphologic assessment of abdominal aortic aneurysms by spiral computed tomographic scanning. *J Vasc Surg* 1997; **26**: 238–46.
17. Chuter TA, Green RM, Ouriel K, DeWeese JA. Infrarenal aortic aneurysm structure: implications for transfemoral repair. *J Vasc Surg* 1994; **20**: 44–50.
18. Balm R, Stokking R, Kaatee R, Blankensteijn JD, Eikelboom BC, van Leeuwen MS. Computed tomographic angiographic imaging of abdominal aortic aneurysms: implications for transfemoral endovascular aneurysm management. *J Vasc Surg* 1997; **26**: 231–7.
19. Schumacher H, Eckstein HH, Kallinowski F, Allenberg JR. Morphometry and classification in abdominal aortic aneurysms: patient selection for endovascular and open surgery. *J Endovasc Surg* 1997; **4**: 39–44.
20. Wolf YG, Fogarty TJ, Olcott C IV, et al. Endovascular repair of abdominal aortic aneurysms: eligibility rate and impact on the rate of open repair. *J Vasc Surg* 2000; **32**: 519–23.
21. Arko FR, Filis KA, Seidel SA, et al. How many patients with infrarenal aneurysms are candidates for endovascular repair? The Northern California experience. *J Endovasc Ther* 2004; **11**: 33–40.
22. Alric P, Hinchliffe RJ, MacSweeney ST, Wenham PW, Whitaker SC, Hopkinson BR. The Zenith aortic stent-graft: a 5-year single-center experience. *J Endovasc Ther* 2002; **9**: 719–28.
23. Carpenter JP, Endologix Investigators. Midterm results of the multicenter trial of the powerlink bifurcated system for endovascular aortic aneurysm repair. *J Vasc Surg* 2004; **40**: 849–59.
24. Cheng SW, Ting AC, Ho P, Poon JT. Aortic aneurysm morphology in Asians: features affecting stent-graft application and design. *J Endovasc Ther* 2004; **11**: 605–12.
25. Ouriel K, Clair DG, Greenberg RK, et al. Endovascular repair of abdominal aortic aneurysms: device-specific outcome. *J Vasc Surg* 2003; **37**: 991–8.
26. AbuRahma AF. Endovascular repair of abdominal aortic aneurysms using 3 commercially available devices: midterm results. *J Endovasc Ther* 2004; **11** (Suppl I): I-2.