Original Article

Vascular Specialist International
Vol. 36, No. 2, June 2020
pISSN 2288-7970 • eISSN 2288-7989
Check for updates

Suitability of the Aortic Neck Anatomy for Endovascular Aneurysm Repair in Korean Patients with Abdominal Aortic Aneurysm

Deokbi Hwang, Jihye Kim, Hyung-Kee Kim, and Seung Huh

Division of Vascular Surgery, Department of Surgery, Kyungpook National University Hospital, Kyungpook National University School of Medicine, Daegu, Korea

Purpose: To evaluate the aortic neck anatomy in Korean patients with abdominal aortic aneurysms (AAAs).
Materials and Methods: We examined computed tomography scans of 343 patients with AAAs (≥5.5 cm for men or ≥5 cm for women) between 2009 and 2018. Eligibility of neck anatomy for endovascular aneurysm repair (EVAR) was assessed with the standard instructions for use (IFU) (length ≥15 mm, suprarenal angulation (SRA) ≤45°, infrarenal angulation (IRA) ≤60°, and diameter 18-32 mm) and the extended IFU (length ≥10 mm, SRA ≤60°, IRA ≤75°, and diameter 17-32 mm).
Results: There were 71 women (20.7%), and 61 patients (17.8%) with rupture. Women had smaller neck diameters (21.3 vs. 23.4 mm, P<0.001 for proximal neck; 22.2 vs. 24.5 mm, P<0.001 for distal neck), and higher angulations (51.5° vs. 37.8°, P<0.001 for SRA; 77.7° vs. 57.0°, P<0.001 for IRA) than men. However, the neck length was not significantly different. Patients with ruptured AAAs had shorter neck lengths (21.0 vs. 26.8 mm, P=0.005) than those with intact AAAs. However, the neck diameters and angulations were not significantly different. EVAR eligibility for standard and extended IFUs was found in 37.5% and 55.1% of men, and 11.3% and 25.4% of women (P<0.001 for both IFUs); neck anatomy was eligible in 34.0% of intact AAAs and 23.0% of ruptured AAAs (P=0.098).
Conclusion: A significant proportion of the Korean patients did not meet the IFU for EVAR, mainly due to the angulated neck. Women, and patients with ruptured AAAs, were less likely to meet the IFU criteria.

Key Words: Abdominal aortic aneurysm, Endovascular procedures, Rupture, Sex, Eligibility determination

Received March 24, 2020
Revised May 9, 2020
Accepted May 18, 2020

Corresponding author: Hyung-Kee Kim
Division of Vascular Surgery, Department of Surgery, Kyungpook National University Hospital, 130 Dongdeok-ro, Jung-gu, Daegu 41944, Korea
Tel: 82-53-420-5605
Fax: 82-53-421-0510
E-mail: hkkim6260@knu.ac.kr
https://orcid.org/0000-0002-4436-7424

This study was presented in the speakers' corner for selected abstracts at the 2019 Leipzig Interventional Course, Leipzig, Germany, January 22-25, 2019.

Vasc Specialist Int 2020;36(2):71-81 • https://doi.org/10.5758/vsi.200016

INTRODUCTION

Endovascular aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) was first described by Parodi et al. [1] in 1991 and has been used commonly over the past two decades [2]. For a successful EVAR, components of the proximal neck anatomy, such as the neck length, angulation, and diameter, are the most critical factors for adequate fixation and sealing at the proximal neck. In cases without these features, a type 1a endoleak can develop and is associated with additional intraoperative procedures, complications, and reinterventions during follow-up [3,4].

According to recent meta-analyses of randomized controlled trials that compared the outcomes between open aortic aneurysm repair (OAR) and EVAR [5,6], EVAR is a less invasive procedure than OAR with lower 30-day mortality and hospitalization length. However, a considerable number of patients are not eligible for EVAR due to constraints in the proximal neck anatomy.

Several factors, such as ethnicity and sex, are known to be associated with suitability for EVAR, with a lower percentage among Asians and women [7,8]. Although there have been a few reports regarding the aortoiliac anatomy of AAAs in Asian patients, the results have been inconsistent because of the small number of patients and the different inclusion criteria for analysis [7,9-11]. Therefore, further work is necessary to investigate the aortoiliac anatomy in Asians, and determine whether there are significant differences between different Asian populations, as well as between Asian and Western patients. This effort may provide benchmarks for future aortic stent graft design for Asians.

The objective of this study was to evaluate the aortic neck anatomy in Korean patients with AAAs, and to compare their suitability for an on-label EVAR according to sex, aneurysm status, and presence/absence of treatment.

MATERIALS AND METHODS

1) Data sources and variables

This study was approved ethically and supervised medically through the Institutional Review Board of Kyungpook National University Hospital (IRB no. KNUH 2020-03-032). The need for informed consent was waived due to the retrospective study design. From January 2009 to June 2018, 388 consecutive patients were registered for an AAA indicated for treatment in our vascular registry, a major tertiary hospital in South Korea. The inclusion criteria were an AAA with a maximal anteroposterior diameter of ≥5.5 cm in men and ≥5 cm in women on computed tomography (CT) scans. After excluding cases of AAA with non-enhancement CT (n=20); an infected AAA (n=6); an AAA associated with vasculitis, such as Behçet's disease or Takayasu's arteritis (n=5); dissecting aneurysm (n=4); and a suprarenal AAA (n=10), a total of 343 patients with AAA were eligible for this study. Iliac artery aneurysms with a small AAA were also excluded.

The suitability of the aortic neck anatomy for EVAR was investigated retrospectively by review of the patients' CT images. To avoid selection bias, CT scans were used regardless of the presence/absence of treatment or treatment type (OAR or EVAR). Moreover, for patients with multiple CT scans, only the most recent scans, before any intervention (when an intervention had occurred), were identified and retained. Data of patient and aneurysm characteristics were analyzed retrospectively, and intraoperative findings during EVAR were collected prospectively.

The outcomes of interest were aortic neck anatomy characteristics and suitability for EVAR according to the standard and extended instructions for use (IFU). The outcomes were also compared with respect to sex and AAA status, and the presence/absence of treatment. In addition, we compared the findings of completion and final angiography among the patients who underwent EVAR according to IFU.

2) Measurement protocols

CT images were processed and reconstructed into three-dimensional images using Aquarius NET software (TeraRecon Inc., San Mateo, CA, USA). The sac diameter, aortic neck length, proximal and distal neck diameter, suprarenal and infrarenal angles, distal aortic diameter, and aortic tortuosity index were examined in all patients. The sac diameter was calculated as the maximum anteroposterior length on CT scans to be compatible with measurements made using a duplex ultrasound for future follow-up. The aneurysm neck was defined as the distance between the lower edge of the lowest renal artery and the beginning of the aneurysm sac. The neck length was determined along the centerline between the lowest renal artery and the beginning of the aneurysm sac by moving a cursor along the centerline path in Aquarius Workstation images. Proximal and distal neck diameters were determined by measuring the outer diameters; if the cross-sectional lumen was not circular and the diameters of major and minor axes were different, the outer diameter of the major axis was considered as the neck diameter. Neck angulation was measured on maximum intensity projection (MIP) images in Aquarius Workstation. In these MIP images, suprarenal or infrarenal angulation points were located at the center of the image, and the image was rotated to enable the suprarenal aorta, aortic neck, and aortic bifurcation to appear in one image; thereafter, the suprarenal and infrarenal angles were calculated (Fig. 1). The aortic tortuosity index was calculated as the difference between the centerline and the straight-line distance between the lowest renal artery and the aortic bifurcation. All measurements were performed by two vascular surgeons (DH and HKK); if the measured values were close to the IFU criteria, two vascular surgeons performed repeated measurements to achieve consensus.

In determining the eligibility of the aortic neck anatomy for EVAR, only the above-mentioned characteristics (neck length, diameter, and angulations) were considered. Factors prone to subjective variation, such as aortic wall calcification, luminal thrombi or atheroma, and shape of the aortic neck (straight or conical), were not taken into consideration.

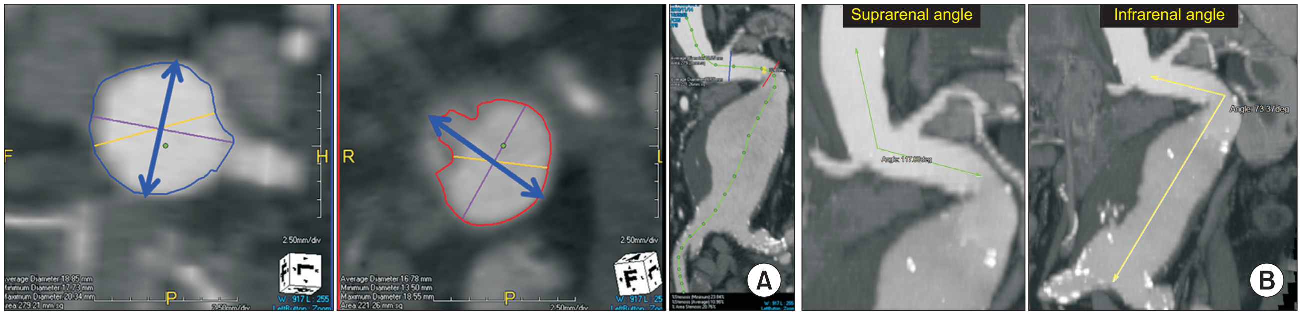

Fig. 1. An example of aortic neck anatomy measurement. (A) Aortic neck diameter and length measurements. Neck length was measured along the centerline between the lowest renal artery and the beginning of the aneurysm sac by moving a cursor along the centerline path in Aquarius Workstation images. Proximal and distal neck diameters were determined by measuring the greatest outer diameters. (B) Measurements of aortic suprarenal and infrarenal angulations. In maximum intensity projection images, suprarenal or infrarenal angulation points were located at the center of the image; the image was then rotated to enable the suprarenal aorta, aortic neck, and aortic bifurcation to appear in one image. Thereafter, the suprarenal and infrarenal angles were calculated.

With regards to determining the neck diameter for suitability for EVAR, the distal neck diameter was considered as a reference value.

3) Definitions

① Standard and extended IFU for neck anatomy

A standard IFU was defined as follows: aortic neck length ≥15 mm, suprarenal angulation ≤45°, infrarenal angulation ≤60°, and neck diameter of 18 to 32 mm according to the strictest IFU of the three currently available devices in Korea (Zenith Endograft; Cook Inc., Bloomington, IN, USA), Endurant IIs (Medtronic Cardiovascular, Santa Rosa, CA, USA), and Incraft systems (Cordis Corporation, Bridgewater, NJ, USA). We added an extended IFU and defined it according to the most liberal IFU criteria of these 3 devices as follows: aortic neck length ≥10 mm, suprarenal angulation ≤60°, infrarenal angulation ≤75°, and neck diameter of 17 to 32 mm. When an unfavorable aortic neck anatomy, including short neck, large angulation, and small or large neck diameters, did not match the IFU criteria, patients were classified into the non-IFU group.

② Completion angiography and final endoleak in EVAR recipients

Angiograms were checked after completion of the endograft placement and prior to the removal of the delivery system; we defined this as completion angiography. If type 1 or 3 endoleaks were present, this was defined as an endoleak at completion angiography. In cases with type 1 or 3 endoleaks, various additional procedures were performed to eliminate them. Despite such additional procedures, the final endoleak was recorded when any suspicious leakage of contrast medium was found from the proximal sealing zone or mid-graft.

4) Data analysis

Results were analyzed using IBM SPSS Statistics ver. 20.0 for Windows (IBM Corp., Armonk, NY, USA). Categorical variables were subjected to chi-squared analysis (if the sample size was adequate) or Fisher's exact test (for smaller samples). For continuous variables, the data are presented as the mean and standard deviation, and Student's independent t-test was used to compare means after confirming normality of distribution. Given the potential for skewness, group comparisons of variables with non-normal distribution relied on the Mann-Whitney nonparametric U-test. Nonparametric tests for correlation analysis (Spearman rank correlation) were used to evaluate the relationship between age and angulations. Partial correlation analysis was performed using the same test to control for the effects of the maximal AAA diameter and neck length. Logistic regression analysis was performed to identify factors associated with final type 1a endoleak in patients who received EVAR. Odds radios with 95% confidence intervals were determined, and statistical significance for all tests was assumed at $P<0.05$.

RESULTS

1) Patient and aneurysm characteristics

The patient characteristics are summarized in Table 1. The mean age of patients was 73 years, and 71 (20.7%) patients were women. Sixty-one (17.8%) patients presented with a ruptured AAA. The most commonly performed treatment during the study period was OAR in 177 patients

https://doi.org/10.5758/vsi.200016

(51.6%, 177/343) followed by EVAR in 95 (27.7%). Fifty-eight patients did not receive any treatment for various reasons, such as poor general condition or the patient's refusal, and 13 were transferred to other hospitals.

The characteristics of the overall neck anatomy are summarized in Table 1 and Fig. 2. The mean length of the aortic neck was 25.7 mm, and the mean suprarenal and infrarenal angles were 40.7° and 61.2°, respectively. The mean diameters of the proximal and distal neck were 23.0 mm and 24.0 mm, respectively. The aortic neck anatomy was suitable for standard IFU in 32.1% of all patients. The most common cause of IFU violation was angulated neck in 39% of patients, and 16% of patients had 2 or more violations (Fig. 2). Even when categorized by sex, a single violation due to angulated neck was the most common cause of IFU violation (33% in men and 61% in women). Two or more violations were demonstrated in 15% of men and 18% of women (Fig. 2).

2) Aneurysm characteristics according to sex

Women with an AAA were significantly older than men with AAA (76.9 vs. 71.5 years, P<0.001). The maximal diameter and neck length of the AAAs were not significantly different according to sex. However, the aortic neck diameter and angulation were significantly different; women had smaller neck diameters and more severe angulation than men (21.3 vs. 23.4 mm for proximal neck diameter, P<0.001; 22.2 vs. 24.5 mm for distal neck diameter, P<0.001; 51.5° vs. 37.8° for suprarenal angulation, P<0.001; 77.7° vs. 57.0° for infrarenal angulation; P<0.001). The mean infrarenal angulation in women exceeded the criteria of both standard and extended IFU.

The proportion of patients who met the standard IFU criteria was significantly lower in women than men (11.3% in women vs. 37.5% in men, P<0.001). The most common factor that did not fit the IFU was infrarenal angulation, and only 24% of women met this criterion (Table 2). The feasibility for EVAR with the extended IFU demonstrated a similar pattern. The proportion of patients that complied with the extended IFU was 55.1% in men and 25.4% in women (P<0.001).

3) Aneurysm characteristics according to status

Sixty-one patients presented with ruptured AAAs; there were no differences in age or sex in terms of ruptured or intact AAAs. The maximal AAA diameter was, of course, larger in those with a ruptured AAA than an intact AAA (73.5 vs. 62.5 mm). Regarding the aortic neck anatomy, the neck diameter and angulations were not significantly different between groups, however, the neck length was significantly shorter in ruptured AAAs than in intact AAAs (21.0 vs. 26.8

Table 1. Clinical characteristics of patients with an AAA

Parameters	Findings (n=343)
Age (y)	72.6±8.4 (35-97)
Female	71 (20.7)
Ruptured AAA	61 (17.8)
Management	
OAR	177 (51.6)
EVAR	95 (27.7)
No interventions	58 (16.9)
Transfer to another hospital	13 (3.8)
Morphology of AAA	
Neck length (mm)	25.7±14.6 (0-69.1)
Suprarenal angulation (°)	40.7±26.6 (0-124.3)
Infrarenal angulation (°)	61.2±28.5 (9.2-135.1)
Diameter, proximal neck (mm)	23.0±3.8 (15.2-38.4)
Diameter, distal neck (mm)	24.0±4.0 (15.3-39.3)
Maximal AAA diameter (mm)	64.5±11.1 (50.0-114.6)
Diameter, aortic bifurcation (mm)	30.8±11.2 (12.6-98.4)
Length of infrarenal abdominal aorta, straight-line (mm)	117.8±16.0 (57.8-182.1)
Length of infrarenal abdominal aorta, centerline (mm)	133.7±19.9 (68.8-197.5)
Aortic tortuosity index	1.14±0.11 (1.01-1.84)

Values are presented as mean±standard deviation (range) or number (%).
AAA, abdominal aortic aneurysm; OAR, open aortic aneurysm repair; EVAR, endovascular aneurysm repair.

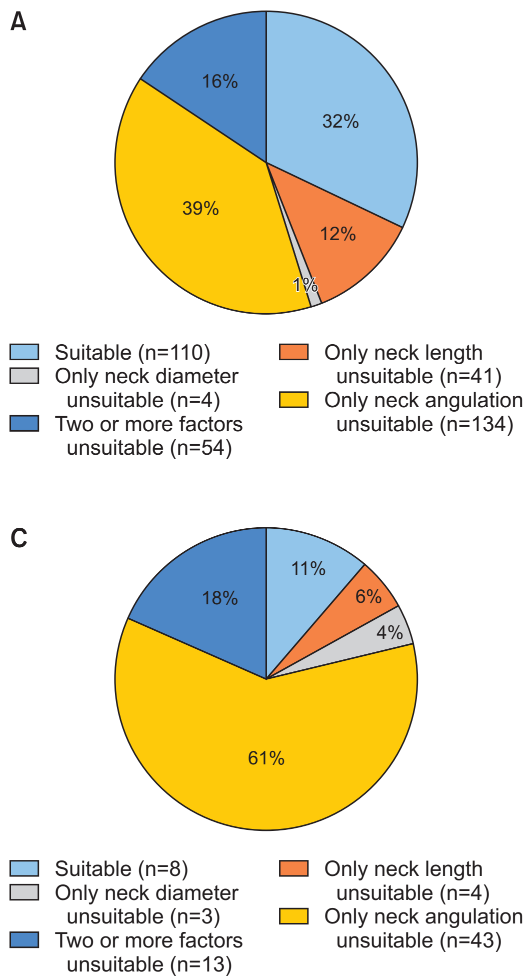

Fig. 2. The distribution of patients according to the suitability for standard instructions for use (IFU) and the number of IFU violations (A) in whole patients (n=343), (B) male patients (n=272), and (C) female patients (n=71).

mm, P=0.005) (Table 3).

The proportion of patients who met the standard and extended IFU criteria was non-significantly lower in those with a ruptured AAA than with those with an intact AAA (23.0% vs. 34.0%, respectively; P=0.098 for standard IFU; 39.3% vs 51.1%, respectively; P=0.120 for extended IFU). The most common factor that did not fit the criteria was infrarenal angulation in the standard IFU (Table 3).

4) Aneurysm characteristics with and without treatment

After exclusion of 13 patients who were transferred to other hospitals, 272 patients received either OAR or EVAR, while 58 did not receive any treatment. Patients without treatment were older (77.6 vs. 71.1 years, P<0.001) and had a higher tendency to be women (29.3% vs. 19.5%, P=0.111) than patients with treatment. The maximal AAA diameters and neck lengths were not significantly different between the treatment/non-treatment groups; however, the neck diameter was larger (23.8 vs. 22.8 mm for proximal neck diameter, P=0.049; 24.9 vs. 23.7 mm for distal neck diameter, P=0.031) and infrarenal angulation was more severe (69.7° vs. 59.3°, P=0.012) in patients without treatment than in patients with treatment (Supplementary Table 1).

5) Subgroup analysis for patients who received EVAR

Ninety-five patients received EVAR using various devices, and the characteristics according to the standard IFU are summarized in Table 4. Among them, 50 patients met the standard IFU criteria for neck anatomy (IFU EVAR group) and 45 patients did not (non-IFU EVAR group). The frequency of type 1a endoleak on completion angiography showed a non-significant trend toward being more prevalent in the non-IFU EVAR group than in the IFU EVAR group. Type 1a endoleaks on completion angiography occurred in 8 (16.0%) patients in the IFU EVAR group and in 14 (31.1%) patients in the non-IFU EVAR group (P=0.094). With the exception of one open conversion performed in the non-IFU EVAR group during surgery, endovascular means were generally used to correct endoleaks. After additional endovascular procedures, the final type 1a en-

https://doi.org/10.5758/vsi.200016

Table 2. Anatomic differences in patients with an AAA according to gender

Parameters	Total (n=343)	Men (n=272)	Women (n=71)	P-value[a]
Age (y)	72.6±8.4	71.5±8.0	76.9±8.7	0.000
Maximal AAA diameter (mm)	64.5±11.1	64.7±11.0	63.9±11.7	0.604
Aortic neck length (mm)[b]	25.7±14.6	26.2±15.3	23.8±11.4	0.298
Aortic diameter, proximal neck (mm)	23.0±3.8	23.4±3.6	21.3±4.1	0.000
Aortic diameter, distal neck (mm)	24.0±4.0	24.5±3.8	22.2±4.3	0.000
Suprarenal angulation (°)	40.7±26.6	37.8±26.2	51.5±25.4	0.000
Infrarenal angulation (°)	61.2±28.5	57.0±27.0	77.7±27.9	0.000
Overall suitability for standard IFU	110 (32.1)	102 (37.5)	8 (11.3)	0.000
Neck length ≥15 mm	260 (75.8)	201 (73.9)	59 (83.1)	0.121
Suprarenal angulation ≤45°	214 (62.4)	182 (66.9)	32 (45.1)	0.001
Infrarenal angulation ≤60°	173 (50.4)	156 (57.4)	17 (23.9)	0.000
Neck diameter 18-32 mm	315 (91.8)	256 (94.1)	59 (83.1)	0.005
Overall feasibility for extended IFU	168 (49.0)	150 (55.1)	18 (25.4)	0.000
Neck length ≥10 mm	290 (84.5)	227 (83.5)	63 (88.7)	0.357
Suprarenal angulation ≥60°	265 (77.3)	216 (79.4)	49 (69.0)	0.008
Infrarenal angulation ≥75°	231 (67.3)	201 (73.9)	30 (42.3)	0.000
Neck diameter 17-32 mm	324 (94.5)	258 (94.9)	66 (93.0)	0.561

Values are presented as mean±standard deviation or number (%).
AAA, abdominal aortic aneurysm; IFU, instructions for use.
[a]Comparison between men and women. [b]Nonparametric Mann–Whitney U-test was used for analysis.

Table 3. Anatomical differences in patients with an AAA according to aneurysm status

Parameters	Intact (n=282)	Ruptured (n=61)	P-value
Age (y)	72.6±8.3	72.7±8.8	0.938
Male	222 (78.7)	50 (82.0)	0.607
Maximal AAA diameter (mm)[a]	62.5±9.5	73.5±13.5	0.000
Aortic neck length (mm)	26.8±14.5	21.0±14.4	0.005
Aortic diameter, proximal neck (mm)	23.1±3.8	22.6±4.1	0.360
Aortic diameter, distal neck (mm)	24.1±4.1	23.8±3.8	0.622
Aortic suprarenal angulation (°)[a]	39.9±25.7	44.1±30.6	0.525
Aortic infrarenal angulation (°)[a]	61.6±27.4	59.6±33.1	0.494
Overall feasibility for standard IFU	96 (34.0)	14 (23.0)	0.098
Aortic neck length ≥15 mm	223 (79.1)	37 (60.7)	0.003
Aortic suprarenal angulation ≤45°	180 (63.8)	34 (55.7)	0.246
Aortic infrarenal angulation ≤60°	142 (50.4)	31 (50.8)	1.000
Aortic neck diameter 18-32 mm	258 (91.5)	57 (93.4)	0.798
Overall feasibility for extended IFU	144 (51.1)	24 (39.3)	0.120
Aortic neck length ≥10 mm	243 (86.2)	47 (77.0)	0.081
Aortic suprarenal angulation ≤60°	223 (79.1)	42 (68.9)	0.093
Aortic infrarenal angulation ≤75°	191 (67.7)	40 (65.6)	0.764
Aortic neck diameter 17-32 mm	266 (94.3)	58 (95.1)	1.000

Values are presented as mean±standard deviation or number (%).
AAA, abdominal aortic aneurysm; IFU, instructions for use.
[a]Nonparametric Mann–Whitney U-test was used for analysis.

Table 4. Characteristics of patients with EVAR according to standard IFU

Parameters	Standard IFU group (n=50)	Non-standard IFU group (n=45)	P-value
Age (y)	72.5±7.9	73.4±8.0	0.572
Female (%)	5 (10.0)	19 (42.2)	0.000
Ruptured AAA	5 (10.0)	3 (6.7)	0.718
Maximal AAA diameter (mm)[a]	60.0±7.9	64.5±10.7	0.030
Aortic neck length (mm)	31.8±12.1	28.2±11.5	0.144
Aortic diameter, proximal neck (mm)	21.6±2.7	20.7±2.7	0.100
Aortic diameter, distal neck	22.4±3.1	21.3±3.4	0.092
Aortic suprarenal angulation (°)[a]	19.2±12.1	47.7±21.5	0.000
Aortic infrarenal angulation (°)[a]	37.3±11.2	72.7±19.0	0.000
Stent-graft model			
Excluder	23	19	
C3	7	7	
Endurant	7	8	
Endurant IIs	8	9	
AFX	3	0	
Zenith	2	2	
Infrarenal fixation device	30 (60.0)	26 (57.8)	0.826

Values are presented as mean±standard deviation, number (%), number only.
EVAR, endovascular aneurysm repair; IFU, instructions for use; AAA, abdominal aortic aneurysm.
[a]Nonparametric Mann–Whitney U-test was used for analysis.

Table 5. Uni- and multivariable model for final type 1a endoleak in patients with EVAR

	Univariable analysis		Multivariable analysis	
	OR (95% CI)	P-value	Adjusted OR (95% CI)	P-value
Female	2.640 (0.647-10.778)	0.224		
Age	1.101 (0.989-1.225)	0.080		
Ruptured AAA	3.810 (0.644-22.523)	0.166		
Maximal AAA diameter	1.038 (0.976-1.103)	0.235		
Neck length	0.979 (0.919-1.043)	0.512		
Distal neck diameter	0.831 (0.645-1.070)	0.150		
Suprarenal angulation	1.028 (1.000-1.058)	0.052		
Infrarenal angulation	1.037 (1.007-1.069)	0.017	1.034 (1.004-1.065)	0.026

EVAR, endovascular aneurysm repair; OR, odds ratio; CI, confidence interval; AAA, abdominal aortic aneurysm.

doleak was not significantly different between groups (6.0% for IFU group [3/50] vs. 13.3% in non-IFU group [6/45], P=0.300). Among 45 patients in the non-IFU group, 36 demonstrated single IFU violation, and 9 showed 2 or more violations. In patients with a single violation, the rate of final type 1a endoleak was 8.3% (3/36); however, the frequency of final type 1a endoleak was 33.3% (3/9) in patients with 2 or more violations (P=0.084).

The results of EVAR according to the extended IFU revealed more prominent results compared to the standard IFU. Sixty-five patients met the criteria of extended IFU, and 30 patients did not. The frequencies of type 1a endoleaks on completion angiography and final type 1a endoleaks were more prevalent in patients who did not meet the extended IFU (37% vs. 17% for type 1a endoleak on completion angiography, P=0.041; 20% vs. 5% for final type 1a endoleak, P=0.026). In multivariable analysis for the risk factors of final type 1a endoleak, infrarenal angulation was associated with final type 1a endoleak (P=0.026) (Table 5).

DISCUSSION

Currently, up to 80% of patients with an AAA are treated with EVAR in Western and Asian countries, and EVAR is considered to be a standard therapy for anatomically suitable patients [12-15]. However, the exact proportion of

https://doi.org/10.5758/vsi.200016

patients that are anatomically fit for EVAR has not been well studied, especially for Asian patients. A recent meta-analysis, mostly comprising Western populations, about the suitability for EVAR demonstrated that the overall pooled estimate of suitability for EVAR was 54% in men and 34% in women [8]. This report was a pooled analysis of 5 studies based on morphological criteria for suitability according to the device IFU including both aortic neck and iliac anatomies. The criteria of angulation and neck diameter was similar to the standard IFU of the current study; however, two studies of this pooled analysis used a neck length of 10 mm for IFU instead of 15 mm. In addition, it is known that the common anatomic barriers for EVAR in Western patients with an AAA are a short neck and large neck diameter, which are more important factors than angulation [16,17].

Few studies have reported the suitability for EVAR among Korean patients. One study from a Korean multicenter registry reported that the mean suprarenal and infrarenal angulations were 33.9° and 46.8°, respectively, and the mean aortic neck length was 35.0 mm [9]; however, this study only included patients undergoing EVAR. Another study demonstrated that the suitability of aortic neck anatomy in Korean patients was 63%, the mean length was 28.0 mm, and the mean infrarenal angulation was 47.5° in 192 patients [10]; however, this study included AAAs more than 4 cm in maximal diameter, so did not represent typical patients requiring treatment.

In our series, we reviewed the neck anatomy of Korean patients with AAAs. Although we only considered neck anatomy without iliac anatomy, the rate of suitability for EVAR was significantly different to that of Western patients and from previous reports of Korean patients with lower rates of EVAR suitability especially in women, and with higher infrarenal angulation as the most common barrier for EVAR. Notably, our series included patients that had OAR or no interventions, as well as EVAR, so as not to bias the anatomic evaluation; this point might have influenced the results with lower suitability for EVAR. As shown in our results, patients without any interventions were older, more often women, and had more complex anatomy for EVAR than patients with interventions.

It is well known that sex is associated with suitability for EVAR. Many reports have reported morphological differences in AAA between sexes, with lower suitability of neck anatomy in women than in men [8,18,19]. However, the results after EVAR, such as immediate and late complications, sac changes, and mortality, are controversial [8,18-20]. In our series, aortic neck diameters and angulations showed significant differences between sexes, with smaller neck diameters and higher angulations in women. In particular, the mean infrarenal angulation in women exceeded the standard, and even extended IFU. Consequently, the proportion of neck anatomy fit for standard and extended IFU in patients who received an EVAR was significantly lower in women than in men (21% vs. 63%, $P<0.001$ for standard IFU; 38% vs. 79%, $P<0.001$ for extended IFU). The rate of type 1a endoleaks at completion angiography was 18.3% (13/71) in men and 37.5% (9/24) in women ($P=0.053$), and final 1a endoleak occurred in 7.0% (5/71) of men and 16.7% (4/24) of women ($P=0.164$). Considering these results together, our study has shown that the aortic neck anatomy of women is not anatomically suitable for EVAR in most Korean patients, and showed a tendency for type 1a endoleak to occur. Furthermore, a recent report suggested that standard EVAR performed on a severely angulated neck has a high incidence of type 1a endoleaks in the long term [21]; therefore, careful follow-up is warranted. In addition, for EVAR in Korean patients, it is necessary to develop and apply flexible devices that can perform well in cases with severe angulated neck because the currently usable devices in South Korea are limited to the Zenith Endograft, Endurant IIs, and Incraft systems. In this study, the most common IFU violation was single violation due to unsuitable neck angulation, in 33% of men and 61% of women. Among the 134 patients with this violation, 127 (94.8%) patients had an infrarenal angulation above 60°. If the IFU of the infrarenal angulation can be raised up to 90°, an additional 78 patients could have received the EVAR within IFU. Therefore, if more flexible devices, such as Aorfix or Anaconda stent grafts (the IFU of these devices is known to be less than 90° for proximal neck angulation), are available, a significant proportion of additional Korean patients can be treated within IFU, although long-term follow-up results for these devices are necessary.

For a ruptured AAA, a recent guideline recommended EVAR over OAR in anatomically feasible patients because of its increasing frequency with experience and a decrease in associated mortality [22]; however, one of the major excluding criteria for EVAR in ruptured AAAs is inadequate neck anatomy. An early randomized trial comparing EVAR and OAR for ruptured AAAs in Western patients revealed that the suitability for EVAR was 46% [23]. In addition, several retrospective and prospective analyses showed a rate of suitable anatomy of 40% to 65% [24-26]. These results are different from those of our present study on Korean patients, which demonstrate that 23% of patients with ruptured AAAs were suitable under standard IFU. Although still controversial, many reports supported that EVAR suitability is associated with better outcomes in patients with ruptured AAAs after OAR [27,28]. In the IMPROVE trial [29], neck length was inversely associated with postoperative mortality in patients who received OAR for a ruptured AAA. In addition, the outcomes were stratified based on the length of the aortic neck, and it was demonstrate that for patients with necks of 5 to 9 mm, the 30-day mortality was 63% for EVAR and 44% for OAR. For patients with neck lengths >30 mm, the mortality in both groups was around 25%. This suggests that patients with suitable necks tend to do better than those with unsuitable necks, regardless of the type of operation offered. In our series, the neck angulations and diameters were not significantly different between cases with ruptured or intact AAAs, but the neck length in those with a ruptured AAA was significantly shorter than those with an intact AAA. In addition, the overall suitability for EVAR with a ruptured AAA was 23%, which was lower than that reported among Western populations. Therefore, OAR for a ruptured AAA among Korean patients still have a role due to the higher rate of IFU violation.

The major limitation of this study is that the analysis was performed on patients from a tertiary referral center without a non-Korean control group. In addition, although we included all patients with AAAs registered to our department, some patients presented to other department with poor general condition and significant comorbidities that may have been missed from analyses. Furthermore, the analysis was only performed on patients with contrast-enhanced CT, and the data of some patients with renal insufficiency were not assessed because they did not undergo contrast-enhanced CT. As a consequence, this study is unlikely to be representative of neck anatomy in all Korean patients with an AAA. However, the majority of EVAR and OAR (70% of EVAR and 86% of OAR) were performed in tertiary hospitals in 2019 [30]; therefore, to some extent, this study may reflect the Korean AAA neck anatomy.

Second, we did not provide any reason for the morphological differences between sexes. However, there are some possible explanations. In our series, the maximal diameters of AAAs were similar in both sexes. However, the straight-line distance from the lowest renal artery to the aortic bifurcation was significantly shorter in women than in men (110.7 vs. 119.7 mm, respectively; P<0.001), while the centerline distance was similar (131.5 for women vs. 134.3 mm for men; P=0.293); therefore, the aortic tortuosity index was greater in women. To undergo a large aneurysm in a confined space, the aortic neck must be short, or angulation must be severe. The maximal diameter of the AAA was correlated with both neck length and angulation in men, but only with neck angulation in women and not with neck length (data not shown). Thus, neck angulation is a prominent feature with increasing size of AAAs in women. In addition, the correlation analysis revealed a positive correlation between age and both angulations (r=0.215, P<0.001 for suprarenal angulation; r=0.226, P<0.001 for infrarenal angulation). After control of maximal AAA diameter and neck length, partial correlation analysis also showed statistical significance between age and both angulations. The angle was severe with age in this analysis; therefore, as women were significantly older than men in the current study, this may explain why the angle in women was severe in this study.

Third, long-term follow-up results of EVAR have not been provided. Intraoperatively, additional procedures, type 1a endoleaks at completion angiography, and final type 1a endoleaks were more prevalent in the non-IFU group than in the IFU group. However, long-term results according to suitable or unsuitable neck anatomy remain controversial. Finally, factors prone to subjective variation, such as aortic wall calcification, luminal thrombi or atheroma, shape of the aortic neck (straight or conical), were not taken into consideration because the distribution of thrombus and calcification in the aortic neck varies depending on the point of measurement, and is related to a somewhat arbitrary measurement. Nonetheless, there is importance in understanding the aortic neck anatomy of Asian patients with an AAA and our study might provide suitable benchmarks for future stent graft design in this ethnic group.

CONCLUSION

A significant proportion of Korean patients with AAAs did not meet the IFU for EVAR, especially due to an angulated neck. Women, and those with a ruptured AAA, were significantly less likely to meet the IFU criteria. Korean patients with AAAs may need to develop and adopt angulated neck-compatible EVAR devices to allow EVAR within IFU; however, long-term follow-up results for these devices are required.

SUPPLEMENTARY MATERIALS

Supplementary data can be found via https://doi.org/10.5758/vsi.200016.

CONFLICTS OF INTEREST

The authors have nothing to disclose.

ORCID

Deokbi Hwang
https://orcid.org/0000-0003-0050-6434
Jihye Kim
https://orcid.org/0000-0002-5164-0783

https://doi.org/10.5758/vsi.200016

Hyung-Kee Kim
https://orcid.org/0000-0002-4436-7424
Seung Huh
https://orcid.org/0000-0002-0275-4960

AUTHOR CONTRIBUTIONS

Conception and design: HKK, SH. Analysis and interpretation: DH, JK, HKK. Data collection: DH, JK, HKK. Writing the article: DH, HKK. Critical revision of the article: HKK, SH. Final approval of the article: DH, JK, HKK, SH. Statistical analysis: DH, HKK. Obtained funding: none. Overall responsibility: HKK.

REFERENCES

1) Parodi JC, Palmaz JC, Barone HD. Transfemoral intraluminal graft implantation for abdominal aortic aneurysms. Ann Vasc Surg 1991;5:491-499.
2) Wigley J, Shantikumar S, Hameed W, Griffin K, Handa A, Scott DJ. Endovascular aneurysm repair in nonagenarians: a systematic review. Ann Vasc Surg 2015;29:385-391.
3) AbuRahma AF, Campbell J, Stone PA, Nanjundappa A, Jain A, Dean LS, et al. The correlation of aortic neck length to early and late outcomes in endovascular aneurysm repair patients. J Vasc Surg 2009;50:738-748.
4) Schanzer A, Greenberg RK, Hevelone N, Robinson WP, Eslami MH, Goldberg RJ, et al. Predictors of abdominal aortic aneurysm sac enlargement after endovascular repair. Circulation 2011;123:2848-2855.
5) Qadura M, Pervaiz F, Harlock JA, Al-Azzoni A, Farrokhyar F, Kahnamoui K, et al. Mortality and reintervention following elective abdominal aortic aneurysm repair. J Vasc Surg 2013;57:1676-1683, 1683.e1.
6) Dangas G, O'Connor D, Firwana B, Brar S, Ellozy S, Vouyouka A, et al. Open versus endovascular stent graft repair of abdominal aortic aneurysms: a meta-analysis of randomized trials. JACC Cardiovasc Interv 2012;5:1071-1080.
7) Banzic I, Lu Q, Zhang L, Stepak H, Davidovic L, Oszkinis G, et al. Morphological differences in the aorto-iliac segment in AAA patients of Caucasian and Asian origin. Eur J Vasc Endovasc Surg 2016;51:783-789.
8) Ulug P, Sweeting MJ, von Allmen RS, Thompson SG, Powell JT; SWAN collaborators. Morphological suitability for endovascular repair, non-intervention rates, and operative mortality in women and men assessed for intact abdominal aortic aneurysm repair: systematic reviews with meta-analysis. Lancet 2017;389:2482-2491.
9) Kwon H, Lee DY, Choi SJ, Park KH, Min SK, Chang JH, et al. Anatomical features and early outcomes of endovascular repair of abdominal aortic aneurysm from a Korean multicenter registry. Vasc Specialist Int 2015;31:87-94.
10) Park KH, Lim C, Lee JH, Yoo JS. Suitability of endovascular repair with current stent grafts for abdominal aortic aneurysm in Korean patients. J Korean Med Sci 2011;26:1047-1051.
11) Cheng SW, Ting AC, Ho P, Poon JT. Aortic aneurysm morphology in Asians: features affecting stent-graft application and design. J Endovasc Ther 2004;11:605-612.
12) Dua A, Kuy S, Lee CJ, Upchurch GR Jr, Desai SS. Epidemiology of aortic aneurysm repair in the United States from 2000 to 2010. J Vasc Surg 2014;59:1512-1517.
13) Joh JH, Park YY, Cho SS, Park HC. National trends for open and endovascular repair of aneurysms in Korea: 2004-2013. Exp Ther Med 2016;12:3333-3338.
14) Tam G, Chan YC, Chong KC, Lee KP, Cheung GC, Cheng SW. Epidemiology of abdominal aortic aneurysms in a Chinese population during introduction of endovascular repair, 1994 to 2013: a retrospective observational study. Medicine (Baltimore) 2018;97:e9740.
15) Choi C, Ahn S, Min SI, Ahn M, Ha J, Yoon HJ, et al. Nationwide epidemiologic study of abdominal aortic aneurysms in Korea: a cross-sectional study using National Health Insurance Review and Assessment service data. Vasc Specialist Int 2019;35:193-201.
16) Timaran CH, Rosero EB, Smith ST, Modrall JG, Valentine RJ, Clagett GP. Influence of age, aneurysm size, and patient fitness on suitability for endovascular aortic aneurysm repair. Ann Vasc Surg 2008;22:730-735.
17) Elkouri S, Martelli E, Gloviczki P, McKusick MA, Panneton JM, Andrews JC, et al. Most patients with abdominal aortic aneurysm are not suitable for endovascular repair using currently approved bifurcated stent-grafts. Vasc Endovascular Surg 2004;38:401-412.
18) Ayo D, Blumberg SN, Gaing B, Baxter A, Mussa FF, Rockman CB, et al. Gender differences in aortic neck morphology in patients with abdominal aortic aneurysms undergoing elective endovascular aneurysm repair. Ann Vasc Surg 2016;30:100-104.
19) Dubois L, Novick TV, Harris JR, Derose G, Forbes TL. Outcomes after endovascular abdominal aortic aneurysm

repair are equivalent between genders despite anatomic differences in women. J Vasc Surg 2013;57:382-389.e1.

20) Nolz R, Schoder M, Baltzer P, Prusa A, Javor D, Loewe C, et al. Application of baseline clinical and morphological parameters for prediction of late stent graft related endoleaks after endovascular repair of abdominal aortic aneurysm. Eur J Vasc Endovasc Surg 2019; 58:24-32.

21) Oliveira NFG, Gonçalves FB, Hoeks SE, Josee van Rijn M, Ultee K, Pinto JP, et al. Long-term outcomes of standard endovascular aneurysm repair in patients with severe neck angulation. J Vasc Surg 2018;68:1725-1735.

22) Chaikof EL, Dalman RL, Eskandari MK, Jackson BM, Lee WA, Mansour MA, et al. The Society for Vascular Surgery practice guidelines on the care of patients with an abdominal aortic aneurysm. J Vasc Surg 2018;67:2-77.e2.

23) Hoornweg LL, Wisselink W, Vahl A, Balm R; Amsterdam Acute Aneurysm Trial Collaborators. The Amsterdam Acute Aneurysm trial: suitability and application rate for endovascular repair of ruptured abdominal aortic aneurysms. Eur J Vasc Endovasc Surg 2007;33:679-683.

24) Reichart M, Geelkerken RH, Huisman AB, van Det RJ, de Smit P, Volker EP. Ruptured abdominal aortic aneurysm: endovascular repair is feasible in 40% of patients. Eur J Vasc Endovasc Surg 2003;26:479-486.

25) van Beek SC, Reimerink JJ, Vahl AC, Wisselink W, Reekers JA, Legemate DA, et al. Outcomes after open repair for ruptured abdominal aortic aneurysms in patients with friendly versus hostile aortoiliac anatomy. Eur J Vasc Endovasc Surg 2014;47:380-387.

26) IMPROVE Trial Investigators, Powell JT, Sweeting MJ, Thompson MM, Ashleigh R, Bell R, et al. Endovascular or open repair strategy for ruptured abdominal aortic aneurysm: 30 day outcomes from IMPROVE randomised trial. BMJ 2014;348:f7661.

27) Barnes R, Kassianides X, Barakat H, Mironska E, Lakshminarayan R, Chetter IC. Ruptured AAA: suitability for endovascular repair is associated with lower mortality following open repair. World J Surg 2014;38:1223-1226.

28) Dick F, Diehm N, Opfermann P, von Allmen R, Tevaearai H, Schmidli J. Endovascular suitability and outcome after open surgery for ruptured abdominal aortic aneurysm. Br J Surg 2012;99:940-947.

29) IMPROVE Trial Investigators. The effect of aortic morphology on perioperative mortality of ruptured abdominal aortic aneurysm. Eur Heart J 2015;36:1328-1334.

30) Healthcare Bigdata Hub [Internet]. Gangwon-do: Health Insurance Review & Assessment Service; C2015 [cited 2020 Mar 13]. Available from: https://opendata.hira.or.kr/.

https://doi.org/10.5758/vsi.200016