Original Article

Anatomical Features and Early Outcomes of Endovascular Repair of Abdominal Aortic Aneurysm from a Korean Multicenter Registry

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Purpose: To introduce a nation-based endovascular aneurysm repair (EVAR) registry in South Korea and to analyze the anatomical features and early clinical outcomes of abdominal aortic aneurysms (AAA) in patients who underwent EVAR.

Materials and methods: The Korean EVAR registry (KER) was a template-based online registry developed and established in 2009. The KER recruited 389 patients who underwent EVAR from 13 medical centers in South Korea from January 2010 to June 2010. We retrospectively reviewed the anatomic features and 30-day clinical outcomes.

Results: Initial deployment without open conversion was achieved in all cases and procedure-related 30-day mortality rate was 1.9%. Anatomic features showed the following variables: proximal aortic neck angle 48.8±25.7° (mean±standard deviation), vertical neck length 35.0±17.2 mm, aneurysmal sac diameter 57.2±14.2 mm, common iliac artery (CIA) involvement in 218 (56.3%) patients, and median right CIA length 34.9 mm. Two hundred and nineteen (56.3%) patients showed neck calcification, 98 patients (25.2%) had neck thrombus, and the inferior mesenteric arteries of 91 patients (23.4%) were occluded.

Conclusion: Anatomical features of AAA in patients from the KER were characterized as having angulated proximal neck, tortuous iliac artery, and a higher rate of CIA involvement. Long-term follow-up and ongoing studies are required.

Key Words: Abdominal aortic aneurysm, Endovascular aneurysm repair, Anatomy, Korean endovascular aneurysm repair registry

INTRODUCTION

After historical studies reported that endovascular aortic aneurysm repair (EVAR) reduces perioperative mortality compared with open surgical repair (OSR) [1-3], EVAR has been increasing worldwide during the last decade. Currently more than half of abdominal aortic aneurysms (AAA) are being treated by EVAR [4-6]. EVAR is increasingly being used not only for elective repair but also for ruptured AAA, with lower perioperative mortality and long-term survival [7,8]. However, current studies showed that there were no differences in all-cause mortality or even in aneurysm-related mortality in the long-term. The rate of reinterventions and graft-related complications were higher for endovascular repair [9,10]

There have been many nationwide and regional registries evaluating the outcomes after EVAR [11-15]. Large size registries can offer more generalized and powerful data especially when momentum is maintained by cooperative feedback of individual participants [11]. Recent registry studies suggested that EVAR showed safe and favorable perioperative outcomes. However, the durability and endoleak after EVAR during long-term follow-up are still challenging problems [12,15]. In the Swedish vascular registry, OSR showed better outcomes compared with EVAR in patients with high risk [14].

Anatomical features of aneurysms are considered main contributing factors that determine the suitability for EVAR [16-20]. The anatomical factors such as aortic neck angle, aortic neck length, aortic neck diameter, iliac artery angulation, iliac diameter, and distal fixation length are usually considered as major determinants [21,22]. In this study, we introduce a nation-based EVAR registry in South Korea and analyze the anatomical features and early clinical outcomes in patients who underwent EVAR.

MATERIALS AND METHODS

1) Registry

The Korean EVAR registry (KER) was a template-based online registry developed and established in 2009. The purpose of the KER was to investigate and share the information and results of EVAR performed in 13 medical centers in South Korea. The study protocol was approved by each center's institutional review board for all patients who underwent EVAR from January 2010 to June 2010. The data was collected retrospectively and all submitted data was analyzed. Preoperative variables included anthropometric data, medical history, concurrent medications, preoperative laboratory findings, etiology (degenerative, infectious, inflammatory, traumatic, congenital), morphology, anatomy, clinical aspects (asymptomatic, intact but symptomatic, contained ruptured, free ruptured), and indication (size, symptom, rupture, complications). Intraoperative data consisted of type of anesthesia, procedure time, device-related information (company, size), additional procedures, femoral access methods, and procedure-related complications. Postoperative variables included length of intensive care unit and hospital stay, perioperative mortality, general and aneurysm-related complications, endoleak, and secondary intervention. Clinical outcome and mortality were measured within ≤30 days after the initial procedure.

2) Definition

Coronary artery disease (CAD) was defined as previous history of myocardial infarction, coronary artery bypass surgery, and percutaneous coronary intervention. Patients presenting with a serum creatinine level >150 μmoL/L (>1.7 mg/dL) were considered as having chronic renal failure (CRF). Chronic obstructive pulmonary disease (COPD) was defined as a forced expiratory volume in one second (FEV$_1$)/forced vital capacity ratio of less than 70% with symptoms of COPD. The American Society of Anesthesiologists (ASA) physical status classification system was used to evaluate preoperative risk. Anatomic features of AAA obtained by preoperative computerized tomography (CT) angiography were reviewed and defined by the following variables (Fig. 1); A1: the most acute angle in the centerline between the suprarenal and infrarenal aorta, A2: the most acute angle in the centerline between the lowest renal artery and the aortic bifurcation. D1: diameter at just below the lowest renal artery, D2: distal neck diameter, D3: maximal diameter of the aneurysm, D4: diameter at the iliac bifurcation, RCIA: lowest diameter of the right common iliac artery, LCIA: lowest diameter of the left CIA, REIA: minimal diameter of the right external iliac artery, LEIA: minimal diameter of the left EIA, RIIA: maximal diameter of the right internal iliac artery, LIIA: maximal diameter of the left IIA, H1: vertical length from the lowest renal artery to the aortic neck, H2: vertical sac length, H3: vertical length from the aneurysm distal end to the iliac bifurcation, H4a: right CIA height, and H4b: left CIA height. Iliac tortuosity grade was determined by the iliac angle, which was the most acute angle in the line between the aortic angle and the common femoral artery [21]: Grade 0 (160°-180°), Grade 1 (121°-159°), Grade 3 (90°-120°), and Grade 3 (<90°). Proximal aortic neck calcification grade was defined as follows: Grade 0 (calcification <25% of circumference), Grade 1 (calcification 25%-50% of circumference), and Grade 2 (calcification >50% of circumference) [21].

3) Device and procedure

EVAR was performed using Gore Excluder (W.L. Gore & Associates Inc., Flagstaff, AZ, USA), Cook Zenith (Cook Medical Inc., Bloomington, IN, USA), Talent and Endurant (Medtronic, Minneapolis, MN, USA), AneuRx (Medtronic, Santa Rosa, CA, USA), and SEAL (S & G Biotech, Seoul, Korea) stent grafts. Device selection and procedure planning was determined by the anatomical feature of the AAA, the patient's risk factors, and comorbidities. The procedures were performed in the operating room or intervention room by a surgeon, interventionist, or cardiologist. Femoral access was performed by surgical cut-down or direct percutaneous puncture. CT angiographies were performed preoperatively and within 30 days after the EVAR procedure.

4) Statistical analysis

The demographic and clinical characteristics of the patients presented by counts and percentages were analyzed using the chi-square and Fisher's exact tests, as appropriate. Comparisons of continuous variables were

Fig. 1. Morphological variables of abdominal aortic aneurysms. A1, the most acute angle in the centerline between the suprarenal and infrarenal aorta; A2, the most acute angle in the centerline between the lowest renal artery and the aortic bifurcation; D1, diameter at just below the lowest renal artery; D2, distal neck diameter; D3, maximal diameter of the aneurysm; D4, diameter at the iliac bifurcation; H1, vertical length from the lowest renal artery to the aortic neck; H2, vertical sac length; H3, vertical length from the aneurysm distal end to the iliac bifurcation; H4a, right common iliac artery height; H4b, left common iliac artery height.

performed by Student's t-test. All statistical analyses were carried out using the PASW Statistics ver. 18.0 (IBM Co., Armonk, NY, USA), with a P-value of ≤0.05 considered statistically significant.

RESULTS

1) Patient demographic and clinical characteristics

The demographic and clinical characteristics of the study patients are presented in Table 1. Patients' mean age at repair was 74.8 years. The comorbidities such as hypertension (n=265, 68.1%), diabetes mellitus (n=62, 15.9%), congestive heart failure (n=13, 3.3%), CAD (n=133, 34.2%), cerebrovascular accident (n=51, 13.1%), CRF (n=37, 9.5%), and COPD (n=53, 13.6%) are also described in Table 1. A total of 96.6% of the patients were included in ASA class I/II/III. There were 21 cases of emergent EVAR due to symptoms suggesting impending rupture and the most common etiology of AAA was degenerative change (n=376, 96.7%).

2) Morphology and anatomical features of AAA

The morphology of the aneurysms as shown in Table 2 and Fig. 1 are described by the following variables (mean±standard deviation [SD]); A1 ($33.9\pm24.5^{\circ}$), A2 ($46.8\pm25.7^{\circ}$), D1 (22.8 ± 11.8 mm), D2 (23.8 ± 5.9 mm), D3 (57.2 ± 14.2 mm), D4 (32.3 ± 16.9 mm), H1 (35.0 ± 17.2 mm), H2 (81.0 ± 61.1 mm), H3 (14.6 ± 27.9 mm), H4a (35.4 ± 16.2 mm), H4b (37.1 ± 17.1 mm), RCIA (17.7 ± 8.1 mm), LCIA (16.4 ± 8.2 mm), REIA (9.6 ± 6.1 mm), LEIA (9.4 ± 6.1 mm), RIIA (9.8 ± 6.9 mm), and LIIA (9.4 ± 5.8 mm). Most cases were fusiform (n=364, 93.6%) and infrarenal (n=384, 98.7%) AAA. Incidence of CIA, IIA, and EIA involvement was 56.3%, 12.5%, and 3.6%, respectively. More than half (n=219, 56.3%) of the patients showed neck calcification, 98 patients (25.2%) had neck thrombus, and the inferior mesenteric artery of 91 patients (23.4%) were occluded. Mean number of lumbar arteries was 5.1 and iliac tortuosity grading was as follows: Grade 0: n=78 (20.1%), Grade 1: n=149 (38.3%), Grade 2: n=94 (24.2%), and Grade 3: n=68 (17.5%) (Table 3). Proximal aortic neck calcification was also graded as follows: Grade 0: n=166 (42.7%), Grade 1: n=180 (46.3%), and Grade 2: n=39 (10.02%) (Table 3).

3) Procedural and clinical outcomes

One hundred fifty patients (38.6%) were treated under general anesthesia. Femoral vascular access was obtained via both femoral cut-down (n=186, 47.8%) or both femoral puncture (n=182, 46.8%). The main body of the endograft was delivered using the right femoral artery in 286 cases
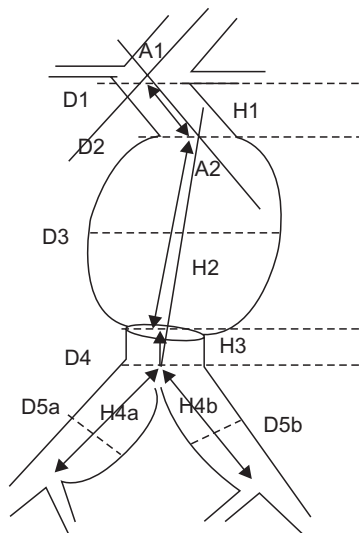
Table 1. Patient demographics and clinical characteristics (n=389)

Characteristic	Value
Age at repair (y)	74.8±7.3
Body mass index (kg/m²)	23.5±3.6
Total cholesterol (mg/dL)	155.9±38.8
Creatinine (mg/dL)	1.57±7.0
Erythrocyte sedimentation rate (mm/h)	29.5±29.2
C-reactive protein (mg/dL)	7.4±28.6
Sex	
Male	339 (87.1)
Female	50 (12.9)
Hypertension	265 (68.1)
Diabetes mellitus	62 (15.9)
Smoking	
Ex-smoker	65 (16.7)
Active smoker	131 (33.7)
Congestive heart failure	13 (3.3)
Coronary artery disease	133 (34.2)
Cerebrovascular accident	51 (13.1)
Chronic renal failure	37 (9.5)
Hypercholesterolemia	122 (31.4)
Chronic obstructive pulmonary disease	53 (13.6)
Symptoms	
No	216 (55.5)
Hypotensive	8 (2.1)
Embolic	5 (1.3)
Pain	49 (12.6)
Mass	83 (21.3)
Other	28 (7.2)
American Society of Anesthesiologists class	
1	39 (10.0)
2	208 (53.5)
3	129 (33.1)
4	8 (2.1)
5	4 (1.0)
6	1 (0.3)
Emergency	
Elective	368 (94.6)
Emergency	21 (5.4)
Etiology	
Degenerative	376 (96.7)
Dissection	5 (1.3)
Infection	4 (1.0)
Inflammation	4 (1.0)

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

Table 2. Morphology of aneurysm

Variable	Value
A1 (angle, °)	33.9±24.5
A2 (angle, °)	46.8 ±25.7
D1 (mm)	22.8±11.8
D2 (mm)	23.8±5.9
D3 (mm)	57.2±14.2
D4 (mm)	32.3±16.9
H1 (mm)	35.0±17.2
H2 (mm)	81.0±61.1
H3 (mm)	14.6±27.9
H4a (mm)	35.4±16.2
H4b (mm)	37.1±17.1
RCIA (mm)	17.7±8.1
LCIA (mm)	16.4±8.2
REIA (mm)	9.6±6.1
LEIA (mm)	9.4±6.1
RIIA (mm)	9.8±6.9
LIIA (mm)	9.4±5.8

Values are presented as mean±standard deviation.
A1, the most acute angle in the centerline between the suprarenal and infrarenal aorta; A2, the most acute angle in the centerline between the lowest renal artery and the aortic bifurcation; D1, diameter at just below the lowest renal artery; D2, distal neck diameter; D3, maximal diameter of aneurysm; D4, diameter at iliac bifurcation; RCIA, lowest diameter of right common iliac artery (CIA); LCIA, lowest diameter of left CIA; REIA, right minimal external iliac artery (EIA) diameter; LEIA, left minimal EIA diameter; RIIA, right maximal internal iliac artery (IIA) diameter; LIIA, left maximal IIA diameter; H1, vertical length from lowest renal artery to aortic neck; H2, vertical sack length; H3, vertical length from aneurysm distal end to iliac bifurcation; H4a, right CIA height; H4b, left CIA height.

(73.5%) and the left femoral artery in 103 cases (26.5%). The Cook Zenith was the most commonly used graft (n=157, 40.4%) during the study period (Table 4). All cases were successfully performed without open conversion or technical failure. Adjunctive procedures during the initial EVAR were needed in 48 cases (12.3%). There were a few adverse events such as limb ischemia (n=4, 1.0%), renal artery occlusion (n=9, 2.3%), pneumonia (n=2, 0.5%), bowel ischemia (n=2, 0.5%), acute renal failure (n=1, 0.3%), iliac artery injury (n=1, 0.3%), and other site bleeding (n=3, 0.8%). There were 124 cases of endoleak including type Ia (n=41, 10.5%), type Ib (n=20, 5.1%), type II (n=65, 16.7%), type III (n=16, 4.1%), and type IV (n=6, 1.5%). Fever related to systemic inflammatory response following EVAR occurred in 217 patients (55.8%) including 103 patients (26.5%) with high fever (≥38°C). Mean hospital stay was 12.1 days (range, 1-155 days) and mean intensive care unit stay was 1.8 days (range, 0-73 days). 30-day all-cause mortality rate was 2.6% (10 patients) and procedure-related mortality rate was 1.9% (Table 5).

Table 3. Anatomical characteristics of aneurysm

Variable	Value
Morphology	
Fusiform	364 (93.6)
Saccular	25 (6.4)
Location	
Infrarenal	384 (98.7)
Juxtarenal	4 (1.0)
Suprarenal	1 (0.3)
Common iliac artery involvement	218 (56.3)
Left	23 (5.9)
Right	51 (13.4)
Both	144 (37.0)
IIA involvement	49 (12.5)
Left	9 (2.3)
Right	13 (3.3)
Both	27 (6.9)
External iliac artery involvement	
Left	8 (2.1)
Right	4 (1.0)
Both	2 (0.5)
Neck calcification	
0	166 (42.7)
1	180 (46.3)
2	39 (10.0)
Neck thrombus	98 (25.2)
IMA occlusion	91 (23.4)
IIA occlusion	
Left	15 (3.9)
Right	14 (3.6)
Both	9 (2.3)
Accessory renal artery	
Left	18 (4.6)
Right	22 (5.7)
Both	6 (1.5)
Lumbar artery (n)	5.1±2.7
Iliac tortuosity grade	
0	78 (20.1)
1	149 (38.3)
2	94 (24.2)
3	68 (17.5)

Values are presented as number (%) or mean±standard deviation.
IIA, internal iliac artery.

Table 4. Procedure related characteristics (n=389)

Variable	Value
Anestheisia	
General	150 (38.6)
Sedation	126 (32.4)
Local	77 (19.8)
Spinal	36 (3.9)
Femoral access	
Both cut down	186 (47.8)
Both puncture	182 (46.8)
Left cut down	4 (1.0)
Left puncture	1 (0.3)
Right cut down	14 (3.6)
Right puncture	2 (0.5)
Main Body	
Left	103 (26.5)
Right	286 (73.5)
Company	
AneuRx (Medtronic)	5 (1.3)
Endurant (Medtronic)	97 (24.9)
Gore Excluder (W.L. Gore & Associates Inc.)	88 (22.6)
SEAL (S & G Biotech)	13 (3.3)
Talent (Medtronic)	29 (7.5)
Cook Zenith (Cook Medical Inc.)	157 (40.4)

Values are presented as number (%).

DISCUSSION

This study describes the anatomical characteristics of abdominal aneurysms in Korean patients and early out-comes after EVAR. Initial deployment without open conversion was achieved in all cases which was similar in result with other recent studies. The Canadian registry also achieved 100%, the DREAM trial reported 97.7%, and the Northern California group achieved 98.7% technical success rate without open conversion [1,12,15]. Our procedure-related 30-day mortality rate (1.9%) seemed to show no significant differences with the ACE (1.3%), EVAR1 (1.78%), and DREAM (1.2%) trials [1,23,24]. Major complication rates (6.2%) were also similar to a recent study from the Northern California group (6.6%) [15] and the primary endoleak rate (n=70, 18.0%) within 30 days in this study was similar to the results of the EUROSTAR trial (17.4%) [13]. In the ACE trial, vascular reinterventions within 30 days occurred in 16%, similar to the OVER trial where 12% of patients underwent a vascular reintervention. However, indications for reintervention were variable in each study group [2,24]. These clinical outcomes suggest that the performance of EVAR in this study was comparable to recent large scale registry studies [1,2,15,23,24].

There have been a few studies which demonstrated the morphologic characteristics of the Asian population [25-27]. These reports described that Asian patients had a small

Table 5. Procedure related complications and outcomes

Variable	Value
Technical success	389 (100)
Adjunctive procedure	48 (12.3)
Major complications	24 (6.2)
Limb ischemia	4 (1.0)
Renal artery occlusion	9 (2.3)
Myocardial infarction	2 (0.5)
Pneumonia	2 (0.5)
Bowel ischemia	2 (0.5)
Acute renal failure	1 (0.3)
Iliac artery injury	1 (0.3)
Other site bleeding	3 (0.8)
All endoleak (patient number)	70 (18.0)
Endoleak Ia	20 (5.1)
Endoleak Ib	7 (1.8)
Endoleak II	20 (5.1)
Endoleak III	4 (1.0)
Endoleak IV	6 (1.5)
More than two	12 (3.2)
More than three	1 (0.3)
Fever (≥37.3°C)	
No	172 (44.2)
Mild fever (<38°C)	114 (29.3)
High fever (≥38°C)	103 (26.5)
Hospital stay (day)	12.1±10.7
Intensive care unit stay (day)	1.8±1.3
Mortality	10 (2.6)
Multi-organ failure	2 (0.5)
Renal failure	1 (0.3)
Respiratory failure	1 (0.3)
Myocardial infarction	1 (0.3)
Bowel ischemia	2 (0.5)
Other	3 (0.8)

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

diameter of the aorta and relatively larger aneurysmal sac diameter, shorter proximal neck, higher incidence of CIA involvement, and short CIA length. When we compare our results with a previous study of Cheng et al. [25], patients in the KER seemed to have smaller aneurysmal sac diameter (mean, 57.2±14.2 mm vs. 62.7±0.9 mm), longer neck length (mean, 35.0±17.2 mm vs. 23.0±9.7 mm), similar incidence of CIA involvement (56.3% vs. 54.9%), and a relatively longer CIA (median right CIA length 34.9 mm vs. 24.7, left CIA length 36.2 mm vs. 28.1 mm). These differences with previous studies appear to be caused by the retrospective nature of the KER and periodic changes in EVAR indications. After recent studies such as the DREAM

and EVAR1 trials suggested that EVAR was associated with higher reintervention rates especially in patients with challenging anatomy [9,10], we selected our patients more strictly according to morphologic characteristics than in the past decade .

Compared with recent studies, aortic tortuosity in our registry seemed to be more prominent. Proximal aortic neck angle (mean±SD, 48.8±25.7°) in the KER was more angulated than the Canadian registry (15±17.8°) and the results from Fulton et al. (26.5±2.6°) [12,18]. Proximal neck angle is known as one of the contributing factors that causes graft migration and endoleak. However, there was no evidence of open conversion, mortality rate, or rupture [18]. We considered proximal neck length, especially vertical length, as a more critical factor that can influence early results of EVAR. Vertical neck length (35.0±17.2 mm) in the KER was longer than the Canadian registry (26.0±11.5 mm) and the results from Fulton et al. (25.6±1.1 mm) [12,18]. It is estimated that sufficient neck lengths can compensate for tortuous neck angles.

Iliac artery tortuosity is associated with a more complex procedure and a higher rate of postoperative complications after EVAR [28]. Our patients showed more tortuous (iliac artery tortuosity index 1.39) iliac arteries than the report (1.2) of Wyss et al. [28]. Our previous study reported that age, smoking, and BMI influenced iliac artery tortuosity [29]. In this study, although iliac seal zone length was relatively enough, tortuosity of the CIA and a high rate of aneurysmal involvement in the iliac artery caused challenges in the EVAR procedures. We needed 48 cases (12.3%) of intra-operative additional procedures after completion of graft deployment especially in patients with hostile anatomy.

The KER recruited 389 patients from 13 medical centers in South Korea. This report is the first brief review introducing the KER and describing anatomical features of Korean patients who underwent EVAR. Each center will continue review and analysis of the data from the KER for allocated subjects such as outcomes for EVAR following ruptured AAA, EVAR for juxtarenal AAA, off-label use in EVAR, parameters which define the fate of type II endoleak, the main cause of stent graft migration, comparison of femoral access, determinants of aneurysm expansion or shrinkage in patients undergoing EVAR, relationship between iliac artery diameter and tortuosity and iliac artery complications, impact of antiplatelet therapy on clinical outcomes and endoleak after EVAR, determinants of endoleak after EVAR, thrombotic occlusion of aneurysmal lumen after EVAR, and thrombotic occlusion of residual lumen of AAA after EVAR in hemodialysis patients.

Our study has several limitations. It was a retrospective study, and the clinical decision whether to perform EVAR or OSR was made by the physicians. Procedure-related

decisions such as anesthesia methods, femoral access and closing devices, choice of grafts, and additional procedures were mainly made by each center. This report shows only early (30 days) outcomes and long-term follow-up is necessary. For a quality improvement in following studies, feedback from all centers and discussions will be needed.

CONCLUSION

Anatomical features of AAA in patients from the KER were characterized as having angulated proximal neck, tortuous iliac artery, and a higher rate of CIA involvement. It is the first nationwide multicenter registry in South Korea and its results were comparable with recent worldwide multicenter EVAR studies. Long-term follow-up and ongoing studies are required.

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