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Comparison of Clinical Outcomes between Surgical Repair and Endovascular Stent for the Treatment of Abdominal Aortic Aneurysm

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Purpose: This study was performed to compare the treatment outcomes between endovascular aneurysm repair (EVAR) and open surgical repair (OSR) of abdominal aortic aneurysms (AAAs) in a South Korean population.

Materials and Methods: We performed a retrospective review of the medical records of 99 patients with AAAs who were managed at Gyeongsang National University Hospital between January 2005 and December 2014. We reviewed the demographic characteristics and perioperative treatment outcomes of patients with AAA undergoing EVAR or OSR. In-hospital mortality and reintervention rates were assessed and compared between the EVAR and OSR groups.

Results: In-hospital mortality was not significantly higher in the OSR group versus the EVAR group (3.8% vs. 8.7%, respectively, P=0.41). Intervention time (209.6 mins vs. 350.9 mins, P<0.001) and length of hospital stay (7.79 days vs. 17.46 days, P<0.001) were significantly longer in the OSR group vs. the EVAR group. Median follow-up time was 24.1 ± 20 months for the EVAR group and 43.9 ± 28 months for the OSR group. The cumulative rate of freedom from reintervention at 60 months was 62.0% for the EVAR group and 100% for the OSR group (P<0.001).

Conclusion: EVAR was favorable in terms of intervention time and length of hospital stay, but the long-term durability of EVAR remains open for further debate.

Key Words: Aorta, Aneurysm, General surgery, Endovascular procedure

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INTRODUCTION

Abdominal aortic aneurysm (AAA) is defined as a localized enlargement of the abdominal aorta such that the diameter is greater than 3 cm or more than 50% larger than the normal diameter [1].

The greater the diameter of AAA, the greater the risk of rupture. If the diameter is greater than 7 cm, the probabil-

ity of rupture is as high as 33%. If ruptured, the mortality rate is 85% to 90% [1]. Therefore, anticipant treatment of AAA is very important, and either endovascular aneurysm repair (EVAR) or open surgical repair (OSR) may be used as treatment. Three notable randomized trials have compared EVAR and OSR [2-4]. All 3 studies showed that EVAR had a lower 30-day mortality rate when compared with OSR, and these results have been supported by large registries

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Department of Thoracic and Cardiovascular Surgery, Institute of Health Science, Gyeongsang National University Hospital, 79 Gangnam-ro, Jinju 52727, Korea Tel: 82-55-750-8121 Fax: 82-55-753-8138 E-mail: jychoi@gnu.ac.kr Conflict of interest: None. [5]. However, the longevity of stent grafting remains an ongoing issue, and research on this issue is scarce in South Korea. Hence, this work was designed to compare the clinical outcomes between OSR and EVAR in a single center in South Korea. Our primary concern was whether EVAR resulted in satisfactory durability.

MATERIALS AND METHODS

1) Study population

A retrospective review of infrarenal type AAA repair in Gyeongsang National University Hospital was carried out between January 2005 and December 2014. Perioperative characteristics were compared between the EVAR group and the OSR group. Cases with intraperitoneal rupture were excluded.

2) Definitions

We defined impending rupture of AAA as (1) a large AAA (diameter >7 cm) with symptoms of acute aortic syndrome; (2) focal discontinuity in circumferential wall calcifications observed on computed tomography (CT); or (3) a well-defined peripheral crescent of increased attenuation within the thrombus of a large AAA on CT (hyperattenuating crescent sign). We defined CT findings of intraperitoneal rupture as (1) a retroperitoneal hematoma adjacent to an abdominal aortic aneurysm; or (2) active extravasation of contrast material [6].

3) Treatments

EVAR was performed by 2 experienced interventional radiologists. All EVAR procedures were performed with bifurcated Zenith (Cook Medical, Bloomington, IN, USA) devices in the earlier years. In 2008 and 2009, Endurant (Medtronic Inc., Minneapolis, MN, USA) devices were used, and from 2010, Gore Excluder (W.L. Gore and Associates Inc., Flagstaff, AZ, USA) devices were used. OSR was performed by 3 experienced surgeons, as a routine procedure. Median laparotomy with infrarenal aorta cross clamp was performed in the usual manner. Depending on the extent of the aneurysm, distal anastomosis was performed on the abdominal aorta, common iliac arteries, external iliac arteries, or femoral arteries.

In patients with an impending or retroperitoneal aortic rupture of the AAA, emergency repair was performed. In the initial period of this study, OSR was preferred in case of emergency. However, as the time elapsed, the use of EVAR increased. Patients with impending or retroperitoneal ruptured AAA were considered anatomically suitable for the EVAR if they met all of the following criteria: 1) minimum length of the infrarenal anchoring segment of 15 mm; 2) an infrarenal neck diameter of 20 to 32 mm; and 3) an ipsilateral iliac artery diameter of 6 to 20 mm, with at least 1 iliac artery able to accommodate an endograft system without obstructing calcifications, tortuosity, or thrombosis.

4) Statistical analysis

All statistical analyses were conducted using IBM SPSS Stastistic ver. 24.0 software (IBM Co., Armonk, NY, USA). We calculated P-value using Fisher's exact or Pearson's chi-square test for categorical variables, and the t-test for continuous variables. Significance was set at P<0.05. To evaluate the risk factors for reintervention, we used logistic regression analysis. In the multivariate model of efficacy, we included relevant variables with P-value <0.3 in the univariate analysis. We calculated associations between the variables included in multivariate analysis, and significance was set at P<0.05.

5) Ethical approval

This retrospective study was approved by the institutional review board of the Gyeongsang National University Hospital (IRB no. GNUH 2017-06-29).

RESULTS

In total, 53 patients underwent EVAR and 46 OSR. Baseline characteristics are shown in Table 1. Patients who received OSR (66.0 ± 9.4) tended to be younger than those who underwent EVAR (72.6 ± 6.4 , P<0.001), which is likely a result of a surgical preference for performing open repair on younger patients. Emergency open repair procedures (P=0.034) were more frequently performed than emergency EVAR. This is probably because, in the beginning period of this study, in situation of emergency OSR was preferred (Fig. 1). The size of the aneurysms in the OSR group was significantly larger than that of the EVAR group (P=0.043). There was no statistically significant difference in the other factors (Table 1).

The differences in treatment outcomes between the EVAR and OSR groups were studied. Intervention time was significantly longer in the OSR group (P<0.001), and length of hospital stay in the OSR group (P<0.001) was more than twice of that in the EVAR group. We assessed complications, such as acute renal failure (ARF), pneumonia, ischemic colitis, peripheral embolic event, and wound problems. Overall, the rate of complication was not significantly

Characteristic	EVAR (n=53)	OSR (n=46)	P-value
		. ,	< 0.001 ^b
Age (y)	72.6 <u>+</u> 6.4	66 <u>+</u> 9.4	
Male	46 (86.8)	39 (84.8)	1.000
Smoking	28 (52.8)	32 (69.6)	0.103
Hypertension	29 (54.7)	28 (60.9)	0.549
Diabetes mellitus	3 (5.7)	9 (19.6)	0.061
Chronic renal failure	6 (11.3)	3 (6.5)	0.498
Stroke	5 (9.4)	3 (6.5)	0.721
Cardiac disease ^a	25 (47.2)	18 (39.1)	0.542
PAOD	10 (18.9)	4 (8.7)	0.164
COPD	8 (15.1)	8 (17.4)	0.790
Statin	14 (26.4)	5 (10.9)	0.073
Antiplatelet drugs	19 (35.8)	11 (23.9)	0.273
Warfarin	1 (1.9)	2 (4.3)	0.596
Emergency	8 (15.1)	16 (34.8)	0.034 ^b
Size of AAA (mm)	61.1±13.7	67.4 <u>+</u> 17.0	0.043 ^b

Table 1. Baseline characteristics of the patients

Values are presented as mean±standard deviation or number (%). EVAR, endovascular aneurysm repair; OSR, open surgical repair; PAOD, peripheral arterial occlusive disease; COPD, chronic obstructive pulmonary disease; AAA, abdominal aortic aneurysm.

^aIncludes stable angina, unstable angina, and acute myocardial infarction.

^bThe data indicate significant differences in statistical comparisons of baseline characteristics.

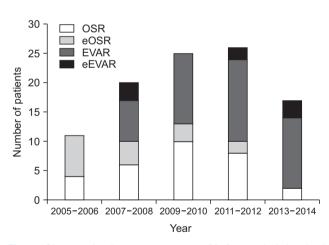


Fig. 1. Changes in the management of infrarenal abdominal aortic aneurysms at Gyeongsang National University Hospital, showing the increasing number of EVAR with time. OSR, open surgical repair; eOSR, emergency OSR; EVAR, endovascular aneurysm repair; eEVAR, emergency EVAR.

different between the 2 groups, except for ARF (P=0.019). Overall rate of in-hospital mortality was 7.7% (n=7). Except for 1 patient with acute respiratory distress syndrome in the OSR group, 3 patients in each group died of hypovo-

Table 2. Treatment outcomes

Treatment outcome	EVAR (n=53)	OSR (n=46)	P-value		
Surgery time (min)	212.5 <u>+</u> 61	350.9 <u>+</u> 97.4	< 0.001 ^a		
Hospital stay (d)	7.9 <u>+</u> 5.6	17.5 <u>+</u> 14.5	< 0.001 ^a		
Complications	18 (34.0)	12 (26.1)	0.412		
Acute renal failure	0	6 (13.0)	0.019 ^a		
Pneumonia	3 (5.7)	3 (6.5)	0.701		
Ischemic colitis	0	1 (2.2)	0.465		
Peripheral embolic event	1 (1.9)	0	1.000		
Wound problem	0	2 (4.3)	0.213		
In-hospital mortality	3 (5.7)	4 (8.7)	0.701		
Reintervention	10 (18.9)	1 (2.2)	< 0.001 ^a		

Values are presented as mean±standard deviation or number (%). EVAR, endovascular aneurysm repair; OSR, open surgical repair. ^aThe data indicate significant differences in statistical comparisons of baseline characteristics.

lemic shock during emergency OSR or EVAR. In-hospital

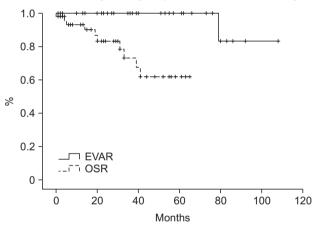


Fig. 2. Cumulative freedom from reintervention rate. EVAR, endovascular aneurysm repair; OSR, open surgical repair.

mortality exhibited no difference between the 2 groups, but the rate of reintervention was significantly higher in the EVAR group than in the OSR group (P<0.001) (Table 2). There were 14 cases of endoleak in the EVAR group. These included 8 cases of type 1 endoleak, of which needed reinterventions (3 required balloon dilatation, 5 required extra stent graft insertion), 5 cases of type 11 endoleak, where 1 case needed embolization, and 1 case of type 111 endoleak, in which aorto-bi-iliac bypass surgery was required. One patient died 1 day after undergoing additional procedures for the type 1 endoleak, and endoleaks of 13 patients resolved as seen on the follow-up computed tomography. Unlike the EVAR group, reintervention of the OSR was only needed in 1 case. This patient developed graft thrombosis 78 months after surgery and required surgical thrombectomy. Rates of freedom from reintervention in the EVAR and OSR groups are shown in Fig. 2.

The results of univariate logistic analysis predicting risk factors for reintervention in the EVAR group are shown in Table 3. Emergency EVAR (P=0.024) was significantly different between the groups. Episodes of reintervention in patients who received emergency EVAR were up to 4.8 times higher. Age, sex, past medical history, drugs taken, and size of AAA were not significantly associated with re-intervention. Further multivariate analysis was conducted with the univariate risk factors exhibiting P-value of <0.3. Emergency EVAR was confirmed again as the risk factor for reintervention (odds ratio [OR], 8.043; 95% confidence interval [CI], 1.698-38.106; P=0.009) (Table 4).

Analyzing the subgroups (elective vs emergency), there was no difference in age and sex between the groups. However, the clinical outcomes between the 2 groups differed. There was a statistically significant longer hospital stay and higher mortality rate in the emergency group (Table 5).

DISCUSSION

Since it was first introduced in 1986, EVAR has advanced tremendously. In the earlier days, the graft-related complication rate after EVAR was as high as 74.6% and up to 56.9% of patients required at least 1 reintervention [7]. One of the earlier endografts (Vanguard endograft) showed significantly higher rates of reintervention [7].

Since then, devices and techniques of EVAR have developed and the results are promising. Several randomized and multicenter clinical trials comparing early outcomes between EVAR and OSR of AAA have been reported. Lederle et al. [4] reported favorable outcomes for the EVAR group in regard to perioperative mortality (0.5% vs. 3%, P=0.004), and there was no significant difference in 2-year mortality (7% vs. 9.8%, P=0.13) for EVAR versus OSR. In addition, the EVAR group exhibited reduced median procedure time, blood loss, transfusion requirement, duration of mechanical ventilation, hospital stay, and intensive care unit stay [4]. Another study showed similar results. In a large randomized controlled trial involving 1,082 elective patients who received either EVAR or OSR, Greenhalgh et al. [2] reported 30-day mortality for EVAR was 1.6% compared with 4.6% for OSR (P=0.007).

Table 3. Univariate logistic regression analysis of risk fac-
tors for reintervention in patients undergoing EVAR (n=53)

		5 5	,
Variable	OR	95% CI	P-value
Age (y)	0.377	0.108-1.309	0.124
Male	0.04	0-248.279	0.470
Smoking	1.666	0.457-6.071	0.439
Emergency	4.783	1.225-18.666	0.024 ^a
Hypertension	0.456	0.117-1.77	0.256
Diabetes mellitus	0.04	0-357.099	0.489
Chronic renal failure	1.153	0.144-9.263	0.893
Stroke	0.046	0-8.073	0.798
Cardiac disease	1.225	0.341-4.398	0.756
PAOD	0.967	0.205-4.565	0.967
COPD	1.796	0.377-8.55	0.462
Statin	1.76	0.488-6.347	0.388
Antiplatelet drug	1.067	0.299-3.8	0.921
Warfarin	0.046	0-54704.785	0.666
Size of AAA	1.537	0.323-7.312	0.589

EVAR, endovascular aneurysm repair; OR, odds ratio; CI, confidence interval; PAOD, peripheral arterial occlusive disease; COPD, chronic obstructive pulmonary disease; AAA, abdominal aortic aneurysm.

^aThe data indicate significant differences in statistical comparisons of baseline characteristics.

Table 4. Multivariate logistic regression analysis of risk factors for reintervention in patients undergoing EVAR (n=53)

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Variable	OR	95% Cl	P-value		
Age (y)	0.111	0.073-1.308	0.111		
Emergency	8.043	1.698-38.106	0.009 ^a		
Hypertension	0.527	0.119-2.34	0.399		

Multivariate analysis includes variables with significant associations in univariate analysis (P<0.3).

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

^aThe data indicate significant differences in statistical comparisons of baseline characteristics.

Table	5.	Comparison	between	elective	and	emergency
treatm	en	t groups				

5 1			
Characteristic and treatment outcome	Elective (n=75)	Emergency (n=24)	P-value
Age (y)	70.1±9.3	70.1±6.5	0.291
Male	64 (85.3)	18 (75.0)	0.350
Size of AAA (mm)	61.2±12.7	72.9 <u>±</u> 20.1	< 0.001
Surgery time (min)	270.1±97.5	295.4 <u>+</u> 128.2	0.015
Hospital stay (d)	10.0 <u>±</u> 7.4	19.8 <u>±</u> 18.0	< 0.001
In-hospital mortality	1 (1.3)	6 (25.0)	<0.001

Values are presented as mean±standard deviation or number (%). AAA, abdominal aortic aneurysm.

Although there are many studies showing promising early outcomes of EVAR compared with OSR, there are doubts about mid-term and long-term results of EVAR. EVAR trial 1 concluded that EVAR offered no advantage with respect to all-cause mortality (after 4 years) and health-related quality of life, was more expensive, and led to a greater number of complications and reinterventions [2]. The rate of reintervention was higher in the EVAR group at all follow-up time-points [8]. In addition, the durability of the endograft remains controversial. There were 25 secondary ruptures after EVAR, but no secondary rupture after open repair [8]. Furthermore, another randomized controlled study showed that, in patients with AAA unfit (poor health status) for OSR, EVAR did not improve survival and was associated with a need for continued surveillance and reinterventions, at a substantially increased cost [9].

Our results are similar to those of previous papers. EVAR had no difference on in-hospital mortality compared with OSR. However, the EVAR group showed shorter median procedure time (P<0.001), shorter hospital stay (P<0.001), and higher rates of reintervention (P<0.001).

We also analyzed the risk factors of reintervention in the EVAR group. Karthikesalingam et al. [10] suggested that most patients requiring reintervention presented symptomatically. They showed that there was no significant difference in reintervention rate between elective and nonelective EVAR [10]. Oranen et al. [11] showed similar results that emergency EVER did not result in higher secondary intervention rates at mid-term at follow-up. However, unlike the results of these studies, emergency EVAR (OR, 8.043; 95% Cl, 1.698-38.106; P=0.009) was an independent risk factor for reintervention in patients with AAA in our study. We propose that further research on this finding is required.

The limitations of this study must be acknowledged. First, all the patients were selected from a single center and this study had a small sample size, which may have caused selection bias. Second, we had a relatively short follow-up period, which limits any conclusions regarding the longterm trends for this disease.

In conclusion, when deciding the approach for treatment of AAA, many risk factors must be considered and patients scheduled to undergo EVAR or OSR should be informed of the advantages and disadvantages of both approaches. Our study showed that EVAR was favorable in terms of time required for procedure, length of hospital stay, in-hospital mortality, and major complications; however, the durability remains a critical issue. We hope that comparison of these findings with other reports will contribute to the enhancement of treatment and management approaches for patients with AAA.

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