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CLINICAL INVESTIGATION ARTERIAL INTERVENTIONS

Type II Endoleak After Endovascular Aortic Aneurysm Repair Using the Endurant Stent Graft System for Abdominal Aortic Aneurysm with Occluded Inferior Mesenteric Artery

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Abstract

Purpose To evaluate the incidence of type II endoleak (EL-II) and aneurysm enlargement after endovascular aneurysm repair (EVAR) using the Endurant stent graft in patients with abdominal aortic aneurysm (AAA) with occluded inferior mesenteric artery (IMA).

Materials and Methods Between 2012 and 2017, 103 patients who underwent EVAR using the Endurant stent graft for AAA with occluded IMA (50 patients with prophylactic embolized IMA and 53 with spontaneous occluded IMA) were retrospectively reviewed. The incidence of EL-II and aneurysm enlargement was evaluated. Predictive factors for persistent EL-II were evaluated based on patient characteristics, preprocedural anatomical characteristics, intraprocedural details, and postprocedural complications.

Results Incidence rates of early EL-II and persistent EL-II were 6.8% (7/103 patients) and 4.9% (5/103 patients), respectively. Aneurysm enlargement was found in 10 patients (9.7%), including all 5 patients with persistent EL-II, 3 with de novo EL-II, and 2 with no EL-II. The rates of freedom from aneurysm enlargement at 1, 2, and 3 years were 98.7%, 97.0%, and 93.1% for the group without persistent EL-II, and 80.0%, 60.0%, and 20.0% for the group with persistent EL-II ($p < 0.001$), respectively. The maximum aneurysm diameter (odds ratio (OR), 1.16; 95% confidence interval (CI), 1.01–1.34; $p = 0.0362$) and the number of patent lumbar arteries (OR, 2.72; 95% CI, 1.07–6.90; $p = 0.0357$) were predictive of persistent EL-II.

Conclusions The incidence of EL-II after EVAR using the Endurant stent graft for AAA with occluded IMA was low, but most early EL-II persisted and resulted in aneurysm enlargement.

Level of Evidence Level 4, Case Series.

Keywords Type II endoleak · Endurant · Inferior mesenteric artery · Prophylactic embolization

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Introduction

Type II endoleak (EL-II) is the most common graft-related complication after endovascular aortic aneurysm repair (EVAR) for abdominal aortic aneurysm (AAA) resulting from backflow from the inferior mesenteric artery (IMA) or other aortic side branches [1, 2]. Persistent EL-II, i.e., EL-II persisting for more than 6 months after EVAR, is reported to be associated with aneurysm enlargement, re-intervention, and even rupture [3–5].

Preoperative patent IMA is thought to be one of the risk factors for EL-II [26–29]. Several reports have shown that prophylactic IMA embolization might be an effective method to reduce the incidence of EL-II [6–11]; however, the precise incidence of EL-II after EVAR for AAA with prophylactic embolized IMA is unknown because previous studies included various types of endograft. The type of endograft can affect the incidence of EL-II [12–14]. For example, an Endurant II™ stent graft system (Endurant stent graft; Medtronic Vascular, Santa Rosa, CA) has been associated with a lower incidence of EL-II than other endografts [15–19]. It is essential to evaluate the efficacy of prophylactic IMA embolization so that we can determine the outcomes of EVAR using a single device for AAA with occluded IMA, including spontaneous occluded IMA and prophylactic embolized IMA.

The purpose of our study was to evaluate the incidence of EL-II and aneurysm enlargement after EVAR using the Endurant stent graft for AAA with occluded IMA.

Materials and Methods

Patient Selection

We retrospectively reviewed medical records and images to identify the 147 patients who had undergone EVAR for unruptured AAA using the Endurant stent graft in our hospital between January 2012 and Jun 2017. Intraprocedural prophylactic embolization for patent IMA was generally performed. Twenty-four patients, who did not attempt or could not undergo IMA embolization due to severe stenosis of the IMA orifice, difficulty in catheterization, or renal insufficiency, were excluded from this study. Twelve patients with a follow-up examination shorter than 6 months, 5 patients without computed tomography (CT) angiography to evaluate the presence of endoleak after EVAR, and 3 patients with developed type I endoleak during follow-up were also excluded. We evaluated the remaining 103 patients with occluded IMA; this group consisted of 50 patients who underwent prophylactic embolized IMA and 53 patients with spontaneous occluded IMA. Patient characteristics are shown in Table 1.

Preprocedural CT Angiography

Preprocedural three-phase CT angiography (non-contrast image, arterial and delayed phases) was performed using a multiple detector computed tomography (MDCT) scanner (Aquilion ONE™, Canon Medical Systems, Japan or SOMATOM Force™, Siemens Healthcare, Forchheim, Germany). A dose of 400 mg I/kg contrast medium was injected at a flow rate of 3 mL/s using an automatic injection system. Bolus tracking system was used with a region of interest (ROI) at the descending aorta. Arterial phase images were obtained 7 s after contrast enhancement of the ROI reached a threshold of 200 Hounsfield Units. Delayed phase images were obtained 35 s after the arterial phase images. The raw scanned images were reconstructed to 1-mm slice thickness. Imaging analysis was performed using Ziosoft 2 software (Ziosoft, Tokyo) by two experienced radiologists. The maximum diameter of the aneurysm was defined as the shortest diagonal from adventitia to adventitia on axial images.

The number of patent lumbar arteries that originated directly from the aneurysm sac was counted. The maximum diameter of lumbar arteries was defined as the largest diameter among those patent lumbar arteries. Iliac aneurysm was defined as common iliac aneurysm, internal iliac aneurysm, and their coexistence. Preprocedural anatomical characteristics are shown in Table 1.

Prophylactic IMA Embolization and EVAR

IMA was selectively catheterized with a 5-F catheter, primarily of the shepherd-hook type. A 1.9-F microcatheter (Carnelian Si; Tokai Medical Products, Aichi, Japan) was advanced coaxially into the IMA just proximal to the origin of the left colic artery, and the IMA main trunk was embolized using a detachable coil (Interlock-18 Fibered IDC occlusion system; Boston Scientific, Natick, MA) and a few pushable coils (Tornado microcoils; Cook Medical, Bloomfield, IN). Embolization was performed until a near-complete stasis in the proximal IMA was achieved. If selective catheterization took more than 15 min, the IMA embolization was terminated (These patients were excluded from this study.) EVAR was performed by the conventional method, following IMA embolization. Internal iliac artery embolization and iliac extension were performed if necessary. Intraprocedural details and postprocedural complications are shown in Table 1.

Follow-up After EVAR

Postprocedural follow-up CT was obtained within 1 month after EVAR, 6 months after EVAR, and at 6-month intervals thereafter. All patients routinely underwent three-phase CT angiography within 1 month with the same protocol as used in the preprocedural CT, and any EL-II detected was designated early EL-II. Patients with early EL-II underwent a follow-up three-phase CT angiography at 6 months. Any EL-II detected during this period was classified persistent EL-II, and spontaneously resolved EL-II was classified transient EL-II. Patients with persistent EL-II underwent non-contrast-enhanced CT at 6-month intervals thereafter in order to follow-up with the aneurysmal size. Patients with transient EL-II underwent non-contrast-enhanced CT at 6-month intervals thereafter,

Table 1 Baseline demographics and operative variables associated with persistent type II endoleak

	All (*N* = 103)	No persistent EL-II (*N* = 98)	Persistent EL-II (*N* = 5)	*p* value
Median follow-up (months)	24.6 ± 14.1	24.3 ± 14.2	30.6 ± 11.1	0.330
Patient characteristics				
Age (years)	76.1 ± 7.4	76.3 ± 7.4	72.8 ± 8.0	0.312
Male gender	96 (93.2%)	91 (92.9%)	5 (100%)	1
Hypertension	87 (84.5%)	82 (83.7%)	5 (100%)	1
Hyperlipidemia	55 (53.9%)	53 (54.6%)	2 (40.0%)	0.66
Diabetes mellitus	17 (16.5%)	17 (17.3%)	0 (0%)	0.588
COPD	23 (22.3%)	22 (22.4%)	1 (20.0%)	1
Coronary artery disease	21 (20.4%)	20 (20.4%)	1 (20.0%)	1
Cerebrovascular disease	15 (14.6%)	13 (13.3%)	2 (40.0%)	0.153
Chronic kidney disease	29 (28.2%)	28 (28.6%)	1 (20.0%)	1
Current smoker	13 (12.6%)	11 (11.2%)	2 (40.0%)	0.119
Anticoagulant therapy	8 (7.8%)	7 (7.1%)	1 (20.0%)	0.338
Antiplatelet therapy	39 (37.9%)	36 (36.7%)	3 (60.0%)	0.364
Preprocedural anatomical characteristics				
AAA diameter (mm)	53.4 ± 7.4	53.0 ± 6.9	60.8 ± 13.1	0.022
Patent IMA	50 (48.5%)	46 (46.9%)	4 (80.0%)	0.196
Number of patent LAs	2.7 ± 1.9	2.6 ± 1.9	4.8 ± 1.3	0.012
Maximum LAs diameter(mm)	1.9 ± 1.2	1.8 ± 1.1	2.9 ± 0.8	0.036
Iliac aneurysm	22 (21.4%)	20 (20.4%)	2 (40.0%)	0.289
IIA occlusion	4 (3.4%)	4 (4.1%)	0 (0%)	1
Intraprocedural details				
IIA embolization	34 (33.0%)	32 (32.7%)	2 (40.0%)	1
IMA embolization	50 (48.5%)	46 (46.9%)	4 (80.0%)	0.196
Stenting for iliac artery dissection	5 (4.9%)	5 (5.1%)	0 (0%)	1
Repair for CFA injury	1(1.0%)	1 (1.0%)	0 (0%)	1
Postprocedural complications				
Limb occlusion	2 (1.9%)	2 (2.0%)	0 (0%)	1
Lymphorrhea	1 (1.0%)	1 (1.0%)	0 (0%)	1

Continuous data are presented as mean ± standard deviation and categorical data as numbers, with percentages in parentheses (univariate logistic regression analysis)

EL-II type II endoleak, *COPD* chronic obstructive pulmonary disease, *AAA* abdominal aortic aneurysm, *IMA* inferior mesenteric artery, *LAs* lumbar arteries, *IIA* internal iliac artery, *CFA* common femoral artery

and three-phase CT angiography at this point was performed when aneurysm enlargement was observed. EL-II detected on the CT angiography was classified as recurrent EL-II. Patients without early EL-II underwent non-contrast-enhanced CT at 6 months post-op and at 6-month intervals thereafter, and three-phase CT angiography at this point was performed when aneurysm enlargement was observed. Any EL-II detected on CT angiography was classified as de novo EL-II. A flowchart regarding follow-up after EVAR is shown in Fig. 1.

Aneurysm enlargement was defined as an enlargement of $\geq$ 5 mm from the preprocedural aneurysm diameter (or the minimum aneurysm diameter during follow-up in the case of re-enlargement after initial shrinking) on CT.

Outcome Measurements

The primary outcome was the incidence of early and persistent EL-II, and the secondary outcome was freedom from aneurysm enlargement. Predictive risk factors for persistent EL-II were also evaluated based on patient characteristics, preprocedural anatomical characteristics, intraprocedural details, and postprocedural complications (Table 1).

Statistical Analysis

Patient characteristics, preprocedural anatomical characteristics, intraprocedural details, and postprocedural complications were summarized as descriptive statistics.

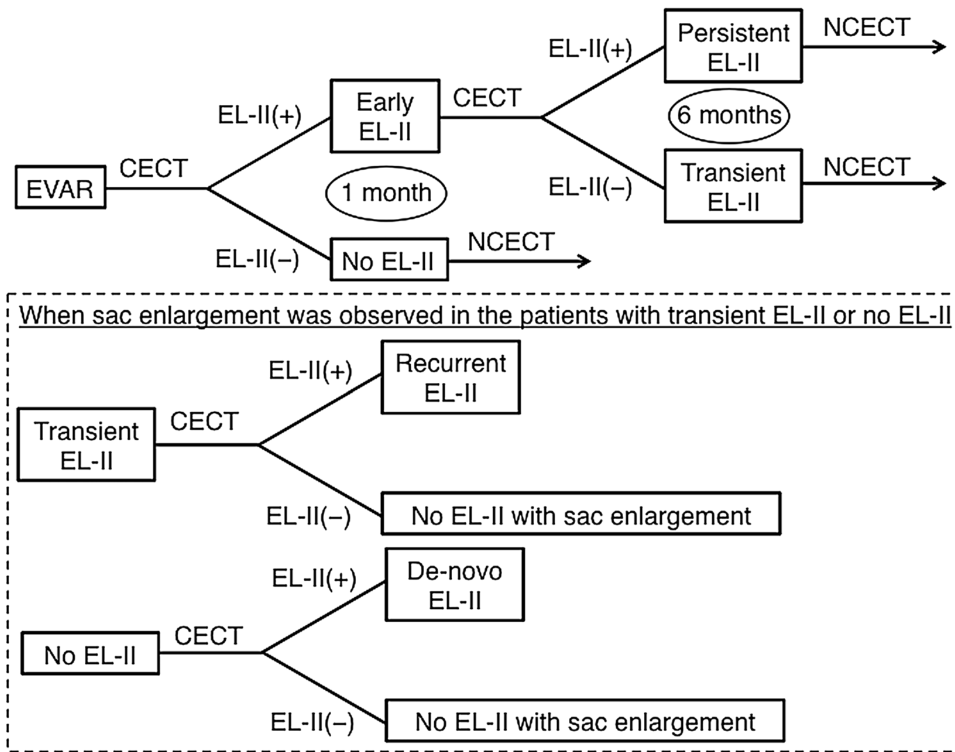

Fig. 1 Flowchart shows the algorithm of the analysis of type II endoleak after EVAR. *EVAR* endovascular abdominal aortic aneurysm repair, *EL-II* type II endoleak, *CECT* contrast-enhanced computed tomography, *NCECT* non-contrast-enhanced computed tomography

Continuous variables were analyzed using Student's *t* test, and qualitative variables were analyzed using Fisher's exact test. Freedom from aneurysm enlargement was assessed using Kaplan–Meier analysis, and the log-rank test was used to compare patients with and without persistent EL-II. Results were obtained from univariate logistic regression analyses investigating variables as potential predictive factors of persistent EL-II and from a multivariate analysis using the variables significant at $p \leq 0.05$ in the univariate analysis. All p values less than 0.05 were considered statistically significant. Statistical analysis was performed with EZR software (Saitama Medical Center, Jichi Medical University, Saitama, Japan) [20].

Results

The Incidence of EL-II

The median follow-up period after the EVAR procedure was 24.6 ± 14.1 months (range 6–61.1). The incidences of early EL-II and persistent EL-II were 6.8% (7/103 patients; 95% confidence interval (CI), 2.8–13.5) and 4.9% (5/103 patients; 95% CI, 1.6–11.1), respectively. Five of 7 (71.4%) cases of early EL-II persisted at 6 months after EVAR. When CT angiography was performed to investigate the cause of aneurysm enlargement, de novo EL-II was found in 3 patients. No patient demonstrated recurrent EL-II. All EL-II resulted from patent lumbar arteries.

Relationship Between Persistent EL-II and Aneurysm Enlargement

Aneurysm enlargement was found in 10 (9.7%) of 103 patients during follow-up. Seven patients demonstrated aneurysm enlargement of ≥ 5 mm from the preprocedural maximum aneurysm diameter. Among these 7 patients, 5 patients had persistent EL-II and 2 had no EL-II. Three patients demonstrated a sac re-enlargement of ≥ 5 mm after initial shrinking, and all 3 patients had de novo EL-II. In summary, among these 10 patients with aneurysm enlargement, 5 (50%) patients had persistent EL-II, 3 (30%) had de novo EL-II, and 2 (20%) had no EL-II. Patients with persistent EL-II had a significantly higher rate of aneurysm enlargement compared to patients without persistent EL-II (100% vs 5.1%; $p < 0.0001$).

The rates of freedom from aneurysm enlargement at 1, 2, and 3 years were 97.5%, 93.9%, and 79.9% in all 103 patients (Fig. 2A), 98.7%, 97.0%, and 93.1% in the group without persistent EL-II, and 80.0, 60.0, and 20.0% in the group with persistent EL-II, respectively (Fig. 2B). There was a significant difference between the groups with and without persistent EL-II ($p < 0.001$). Among 10 patients with aneurysm enlargement, 4 patients underwent transarterial embolization or open conversion for EL-II, and 6

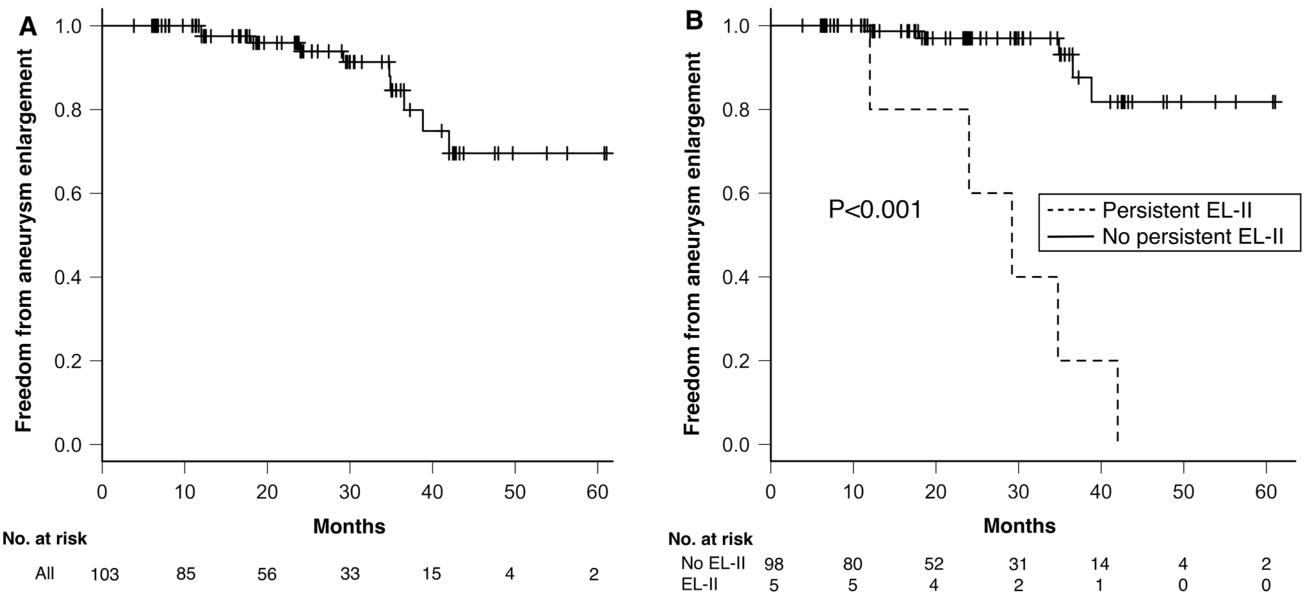

Fig. 2 **A** Kaplan–Meier analysis of freedom from aneurysm enlargement in all 103 patients. **B** Kaplan–Meier analysis of freedom from aneurysm enlargement in the patients with and without persistent type II endoleak (EL-II)

patients were followed-up without any interventions. No patients demonstrated aneurysm rupture during follow-up.

Risk Factor Analysis for Persistent EL-II

In univariate analysis, the maximum aneurysm diameter (60.8 ± 13.1 vs 53.0 ± 6.9; $p = 0.02$), the maximum diameter of patent lumbar arteries (2.9 ± 0.8 vs 1.8 ± 1.1; $p = 0.04$), and the number of patent lumbar arteries arising from the AAA sac (4.8 ± 1.3 vs 2.6 ± 1.9; $p = 0.01$) were significantly higher in patients with persistent EL-II (Table 1). In a multivariate logistic regression analysis, the maximum aneurysm diameter (odds ratio (OR), 1.16; 95% CI, 1.01–1.34; $p = 0.0362$) and the number of patent lumbar arteries (OR, 2.72; 95% CI, 1.07–6.90; $p = 0.0357$) were predictive of persistent EL-II (Table 2).

Table 2 Multivariate logistic regression analysis for persistent type II endoleak

Predictor	Odds ratio (95% CI)	*p* value
Maximum aneurysm diameter	1.16 (1.01–1.34)	0.0362
Number of patent lumbar arteries	2.72 (1.07–6.90)	0.0357

CI confidence interval

Discussion

The results of the 15-year follow-up of the EVAR trial 1 revealed that aneurysm-related and total mortality were greater at the late follow-ups for patients who had EVAR than for those who had open repair [21]. The predominant cause of aneurysm-related deaths was secondary aneurysmal sac rupture. EL-II is a well-known risk factor of delayed aneurysm enlargement and is expected to be related to rupture [3–5]. Therefore, to improve the long-term outcomes of EVAR, it is important to treat and prevent EL-II. Transarterial embolization [22] and direct sac puncture [23] are the most common approaches for treating EL-II. The technical success rate of these interventions is variable, but more than 60% of treated aneurysms continue to enlarge and require additional treatment or even open conversion [24, 25].

Preoperative patent IMA was thought to be an independent risk factor of EL-II [26–29]. Prophylactic IMA embolization was believed to be a logical way to reduce the incidence of EL-II. The incidence of early EL-II after EVAR with occluded IMA has been reported to be 13.9–19.4%, but that of EL-II with patent IMA after EVAR was found to be 32.6–42% [8, 11, 30]. However, these previous studies included various types of endografts, which could have impacted the results, since some reports have shown an association between the type of endograft and the incidence of EL-II. In other studies, the occurring rates of early EL-II for patients treated with Zenith (Cook Medical, Bloomington, IN), Excluder (W.L. Gore and Associates, Flagstaff, AZ), and Endurant stent grafts ranged from 12.2 to 23% [13, 31], 23.5 to 40% [31, 32], and 9.1 to 16.3% [15–19], respectively. The differences of mechanical properties or fabric porosity of fabric may affect the intra-aneurysm pressure after EVAR and the incidence of EL-II [12, 26]. However, there have been little studies regarding this mechanism. Our study demonstrated that the incidence of early EL-II after EVAR using a single endograft (in this case the Endurant stent graft) in patients with occluded IMA was 6.8%. This incidence is lower than in previous studies of EVAR using the Endurant stent graft.

In our study, the incidence of persistent EL-II after EVAR with the Endurant stent graft was as low as 4.9%, versus 11.6% in a previous report [15]. However, 5 of 7 (71.4%) early EL-II cases in our study persisted for more than 6 months even though 36.1–79.9% of early EL-II cases were reported to disappear spontaneously [3, 33–35]. It is also notable that all persistent EL-II cases resulted in aneurysm enlargement in our study. EL-II after EVAR with occluded IMA may be considered a "malignant" form of EL-II, and it may be better to treat this aggressively.

The number of patent lumbar arteries and the maximum diameter of the aneurysm were predictive factors of persistent EL-II in our study as in previous studies; however, some reported predictive factors such as large lumbar artery [37, 38], increasing age [28], and the absence of chronic obstructive pulmonary disease [12] were not significant in our study. Several studies have shown that an increasing number of patent lumbar arteries was a risk factor of persistent EL-II, as in our present results [36–39]. All 5 of our patients with persistent EL-II had multiple patent lumbar arteries, and all EL-II was derived from patent lumbar arteries. In addition to prophylactic IMA embolization, lumbar artery embolization may be effective for reducing the incidence of persistent EL-II [39].

Our study has some limitations. The main concern is that this is a retrospective single institute study and that the number of patients with EL-II is small. Therefore, the level of evidence is low and statistical analysis for predictive factors of EL-II lacks in robustness, owing to the small number of patients with EL-II. We are now starting to conduct a prospective and multi-center study of preoperative IMA and lumbar artery embolization (The clinical trial identifier is UMIN000031042.) In addition, the patients without early EL-II only underwent non-contrast-enhanced CT unless aneurysm enlargement occurred. Therefore, occult recurrent EL-II or de novo EL-II without aneurysm enlargement could have been present in more patients. However, it was not a clinical problem at the current stage of this study. Even in cases with occult EL-II or cases without EL-II, aneurysm enlargement may occur in the future, and further clinical follow-up is required to address it.

As for the method used in this study, compared to the standard amount, the dose of contrast medium (400 mg I/kg) used for CT angiography may have been set smaller in our study. This protocol has been used because the patients with AAA often had renal insufficiency or often underwent repeated contrast studies (contrast-enhanced CT or angiography). The contrast medium at a dose of 400 mg I/kg was thought to be sufficient to evaluate AAA as described previously [40, 41].

Conclusions

The incidence of EL-II after EVAR using the Endurant stent graft for AAA with occluded IMA is low, but most cases that do occur after this procedure result in persistent EL-II and further aneurysm enlargement. Thus, since the specific form of EL-II we address in this study is unlike other the EL-II in its persistent, it is a potential candidate for additional and aggressive treatment.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflicts of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. The institutional review board approved this retrospective study.

Consent for Publication Consent for publication was obtained for the data of every individual person's data included in the study.

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