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Endovascular versus open repair in patients with abdominal aortic aneurysm: a claims-based data analysis in Japan

Yuki Kimura,[1] Hiroshi Ohtsu ,[1,2,3] Naohiro Yonemoto,[4,5] Nobuyoshi Azuma,[6] Kazuhiro Sase [1,3]

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For numbered affiliations see end of article.

Correspondence to
Dr Kazuhiro Sase;
sase@juntendo.ac.jp

ABSTRACT

Objectives Endovascular aortic repair (EVAR) evolved through competition with open aortic repair (OAR) as a safe and effective treatment option for appropriately selected patients with abdominal aortic aneurysm (AAA). Although endoleaks are the most common reason for post-EVAR reintervention, compliance with lifelong regular follow-up imaging remains a challenge.

Design Retrospective data analysis.

Setting The Japan Medical Data Center (JMDC), a claims database with anonymous data linkage across hospitals, consists of corporate employees and their families of ≤75 years of age.

Participants The analysis included participants in the JMDC who underwent EVAR or OAR for intact (iAAA) or ruptured (rAAA) AAA. Patients with less than 6 months of records before the aortic repair were excluded.

Main outcome measures Overall survival and reintervention rates.

Results We identified 986 cases (837 iAAA and 149 rAAA) from JMDC with first aortic repairs between January 2015 and December 2020. The number of patients, median age (years (IQR)), follow-up (months) and post-procedure CT scan (times per year) were as follows: iAAA (OAR: n=593, 62.0 (57.0–67.0), 26.0, 1.6, EVAR: n=244, 65.0 (31.0–69.0), 17.0, 2.2), rAAA (OAR: n=110, 59.0 (53.0–59.0), 16.0, 2.1, EVAR: n=39, 62.0 (31.0–67.0), 18.0, 2.4). Reintervention rate was significantly higher among EVAR than OAR in rAAA (15.4% vs 8.2%, p=0.04). In iAAA, there were no group difference after 5 years (7.8% vs 11.0%, p=0.28), even though EVAR had initial advantage. There were no differences in mortality rate between EVAR and OAR for either rAAA or iAAA.

Conclusions Claims-based analysis in Japan showed no statistically significant difference in 5-year survival rates of the OAR and EVAR groups. However, the reintervention rate of EVAR in rAAA was significantly higher, suggesting the need for regular post-EVAR follow-up with imaging. Therefore, international collaborations for long-term outcome studies with real-world data are warranted.

WHAT IS ALREADY KNOWN ABOUT THIS SUBJECT?

⇒ Endovascular aortic repair (EVAR) has evolved through competition with open aortic repair (OAR) as a safe and effective treatment option for appropriately selected patients with abdominal aortic aneurysm (AAA).

⇒ Although annual follow-up with imaging is recommended for EVAR, long-term surveillance and data collection remain challenging.

WHAT ARE THE NEW FINDINGS?

⇒ Claims-based analysis in Japan showed no statistically significant difference in 5-year mortality of EVAR compared with OAR.

⇒ However, EVAR had a significantly higher reintervention rate in ruptured AAA, and a long-term upward trend offset the initial benefit in intact cases.

HOW MIGHT THESE RESULTS AFFECT FUTURE RESEARCH OR SURGICAL PRACTICE?

⇒ Lifelong regular follow-up with imaging is recommended at 30 days post-EVAR and annually thereafter.

⇒ International collaborations to create real-world surveillance systems are warranted.

INTRODUCTION

Although abdominal aortic aneurysms (AAA) are asymptomatic, they tend to enlarge, and ruptured cases have a high mortality rate. The exact number of patients with AAA is unknown, but it is estimated to be approximately 1.4% of the population between 50 and 84 and is more common in men and smokers.[1 2]

Treatment of AAA includes open aortic repair (OAR) and endovascular aortic repair (EVAR), as updated in the practice guidelines by the Society for Vascular Surgery (SVS),[3] the European Society for Vascular Society (ESVS),[4] and the Japanese Society for Vascular Surgery (JSVS).[5] In addition, collaborations for quality improvement such as VASCUNET, Vascular Quality Initiative (VQI), and International Consortium of Vascular Registries (ICVR) have helped to

improve the outcomes of patients with intact (iAAA) and ruptured (rAAA) AAA.[6]

EVAR has evolved as a safe and effective treatment option for appropriately selected AAA patients through competition with OAR.[3–5] Although EVAR has an advantage in perioperative outcomes, aneurysm sac failure to regress after EVAR is associated with lower long-term survival.[7] Endoleaks are the most common reason for aortic reintervention.[8] Current guidelines recommend follow-up imaging at 30 days post-EVAR and annually thereafter.[3] However, the imaging follow-up compliance is reported to be only about 40%.[3] Therefore, the US Food and Drug Administration (FDA) recently issued a letter to healthcare providers to recommend lifelong annual follow-up imaging and create a real-world surveillance system.[9]

Real-world evidence (RWE) is a new concept in regulatory science to appraise fit-for-purpose reliability and relevance of real-world data (RWD).[10 11] Since there are limitations with registry-based research in vascular medicine,[12] health insurance claims have been used as a promising source of RWD with high external validity because there is no reimbursement without billing the payer.[13–18] Recently, a patient-level claims database with an anonymous data-linkage system was developed in Japan and used in various areas of medical research.[19–21] In this study, we aimed to examine the relevance of the claims database and evaluate the long-term outcome of EVAR and OAR for the treatment of AAA.[13 15 16]

METHODS

Study design and data source

This retrospective cohort study used anonymized patient-level claims data from the Japan Medical Data Center (JMDC, Tokyo).[19] The JMDC is one of the largest databases in Japan, with approximately 9.8 million beneficiaries of ≤75 years of age or 7.8% of the Japanese population registered as of 2021.[20] The Japanese universal health insurance system is based on Fee-for-Service (FFS) and Diagnosis Procedure Combination (DPC).[22] While the Diagnosis Related Group (DRG) in the USA is a pay-per-case system, the DPC is a pay-per-day system with a blanket portion for basic hospital fees and an FFS portion, including surgical procedures and expensive devices. Therefore, missing data are rare for expensive imaging and surgeries.[13] The JMDC anonymously links monthly billing receipts routinely collected from DPC hospitals, FFS clinics, and pharmacies to provide a patient-centric database.[20] In this study, the codes from the JMDC, based on the International Classification of Diseases, 10th Edition (ICD-10), the Anatomical Therapeutic Chemical Classification (ATC), and specific billing codes for medical devices, are designated by square brackets.

Patient selection

We have designed our patient selection flow from the JMDC claims database (figure 1) based on a previously published study from Germany.[13] Patients with a diagnosis code of rAAA [I713] or iAAA [I714], with their first procedure code for OAR [150245110, 150245210] or EVAR [150301410, 150301510, 150400410] (online supplemental table 1) between January 2015 and December 2020 were selected. We associated diagnosis codes, tests, prescriptions, and procedure codes based on monthly insurance claims. We excluded patients with procedure codes for thoracic aorta (online supplemental table 1) during their first procedure for AAA. The first submitted procedure was considered the primary case. Patients with less than 6 months of JMDC enrollment were also excluded from primary procedures.

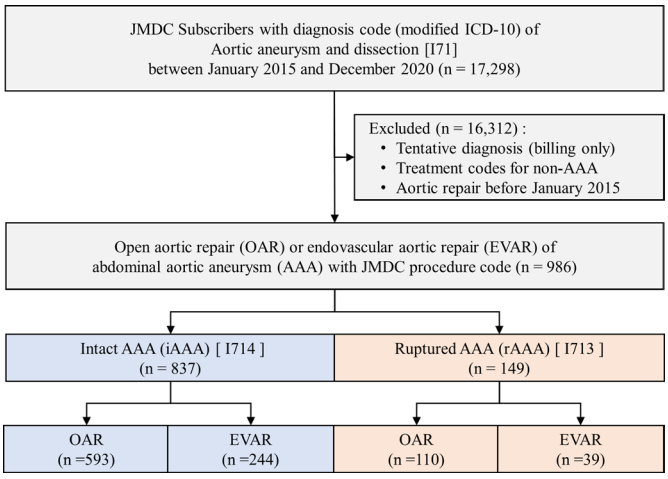

Figure 1 Study flow chart. Study flow chart of patient selection: 986 patients who underwent AAA intervention between January 2015 and December 2020 were included in the analysis. AAA, abdominal aortic aneurysm; EVAR, endovascular aortic repair; JMDC, Japan Medical Data Center; iAAA, intact abdominal aortic aneurysm; ICD-10, International Classification of Diseases, 10th Edition; rAAA, ruptured abdominal aortic aneurysm; OAR, open aortic repair.

Ethical consideration

The Research Ethics Committee, Faculty of Medicine, Juntendo University approved the protocol of this study (E21-0163-M01) according to the Ethical Guidelines for Medical Research Involving Human Subjects (Ministry of Health, Labour, and Welfare of Japan) and the World Medical Association (WMA) Declaration of Helsinki. The need for informed consent was waived in this observational study owing to the anonymity of the data.

Preoperative risk factors

Preoperative risk factors[1] including hypertension [I10-I15], dyslipidemia [E78], diabetes mellitus [E10-E14], chronic obstructive pulmonary disease (COPD) [J44], cerebrovascular disease [I63], renal failure [N17–N18], atrial fibrillation [I48], heart failure [I50], ischemic heart disease [I20–I25], prescription of antiplatelet agents [B01C], prescription of direct oral anticoagulants [B01F, B01E], warfarin [B01A], and smoking history. The Japanese claims data contain a 'tentative disease code' for billing purposes.[22–24] Therefore, to increase specificity,

we combined the codes for the diagnosis, prescription, and treatment of hypertension, dyslipidemia, diabetes mellitus, COPD, cerebrovascular disease, renal failure, heart failure, and ischemic heart disease within the same billing month.[21] We have defined smoking before the index date based on the smoking history described in previous studies using the JMDC.[25]

Outcomes

Postoperative outcomes including cerebrovascular disease [I63], thromboembolism [I802, I822], disseminated intravascular coagulation (DIC) [D65], renal failure [N17–N18], CT follow-up rate, reintervention, 30-day mortality, and 5-year mortality were studied. Cerebrovascular disease, thromboembolism, DIC, and renal failure were defined by a combination of diagnosis and prescription or procedure. The death flags in the subscribers and diagnoses tables have been integrated with withdrawals not elsewhere classified within 1 month after the index. We defined reintervention after OAR and EVAR as the first AAA-related procedure code (online supplemental table 1) billed in the month following the primary procedure or later, which is consistent with prior works.[14–17] The CT follow-up rate was calculated as the number of CT scans performed per year of follow-up after the initial procedure.

Statistical analysis

The data of the patients who withdrew from insurance were considered censored data, and all patients were included in the analyses. Categorical variables were summarized by count (percentage) and were compared using Fisher's exact test, and continuous variables were summarized by median (IQR) and were compared using the Wilcoxon rank-sum test. Survival curves were evaluated using the Kaplan-Meier method with the log-rank test. Multivariable Cox proportional hazards models were used to estimate HRs and 95% CIs, adjusting for baseline variables. All analyses maintained the standard definition of statistical significance as a two-tailed α risk of 0.05 or less. Statistical analyses were conducted using SAS V.9.4 (SAS Institute).

RESULTS

Data source and patient selection

Figure 1 shows the flow chart of patient selection. A total of 17,298 patients with ICD-10 code for aortic aneurysm and dissection [I71] were selected from among those registered in the JMDC database. Between January 2015 and December 2020, 986 patients underwent the first repair for AAA. Of these, 149 patients had an rAAA (39 EVAR and 110 OAR cases), and 837 patients had an iAAA (244 EVAR and 593 OAR cases).

Patient background and risk factors

Baseline demographics, comorbidities, and clinical characteristics of JMDC patients who underwent OAR and EVAR are shown in table 1. In the iAAA group, the most notable differences between OAR and EVAR were

Table 1 Baseline patient characteristics

	iAAA					rAAA				
	n=837					n=149				
	OAR		EVAR			OAR		EVAR		
Variables	n=593		n=244		P value	n=110		n=39		P value
Age, median (IQR)	62.0	(31.0–69.0)	65.0	(31.0–69.0)	<0.0001*	59.0	(53.0–59.0)	62.0	(59.0–67.0)	<0.0001*
Female gender, n (%)	74	12.5%	10	4.1%	<0.0001†	12	10.9%	3	7.7%	0.76†
Hypertension, n (%)	377	63.6%	158	64.8%	0.81†	80	72.7%	26	66.7%	0.54†
Dyslipidemia, n (%)	209	35.2%	96	39.3%	0.27†	34	30.9%	12	30.8%	1.00†
Diabetes, n (%)	87	14.7%	33	13.5%	0.74†	18	16.4%	6	15.4%	1.00†
COPD, n (%)	1	0.2%	2	0.8%	0.21†	0	0.0%	0	0.0%	–†
Cerebrovascular accident, n (%)	38	6.4%	8	3.3%	0.09†	4	3.6%	2	5.1%	0.65†
Kidney failure, n (%)	12	2.0%	4	1.6%	1.00†	12	10.9%	3	7.7%	0.76†
Atrial fibrillation, n (%)	78	13.2%	25	10.2%	0.30†	20	18.2%	3	7.7%	0.20†
Chronic heart failure, n (%)	167	28.2%	67	27.5%	0.87†	34	30.9%	8	20.5%	0.30†
Ischemic heart disease, n (%)	147	24.8%	59	24.2%	0.93†	16	14.5%	5	12.8%	1.00†
Coronary angiography, n (%)	192	32.4%	60	24.6%	0.03†	22	20.0%	5	12.8%	0.47†
Antiplatelet agent, n (%)	260	43.8%	113	46.3%	0.54†	32	29.1%	11	28.2%	1.00†
Oral anticoagulant, n (%)	74	12.5%	34	13.9%	0.57†	20	18.2%	2	5.1%	0.06†
Smoking, n (%)	240	40.5%	105	43.0%	0.54†	40	36.4%	14	35.9%	1.00†

Categorical values are reported as total numbers (%) and continuous variables as medians (IQR).
*Wilcoxon rank-sum test.
†Fisher's exact test.
COPD, Chronic Obstructive Pulmonary Disease ; EVAR, endovascular aortic repair; iAAA, intact abdominal aortic aneurysm; OAR, open aortic repair; rAAA, ruptured abdominal aortic aneurysm.

Table 2 The postoperative outcomes

Variables	iAAA n=837 OAR n=593		iAAA n=837 EVAR n=244		P value	rAAA n=149 OAR n=110		rAAA n=149 EVAR n=39		Pvalue
Follow-up months, median (IQR)	26.0	(13.0–39.0)	17.0	(7.0–30.5)		16.0	(7.0–31.0)	18.0	(5.0–41.0)	
Cerebrovascular accident, n (%)	12	2.0%	2	0.8%	0.373	2	1.8%	2	5.1%	0.280
Venous thromboembolism, n (%)	53	8.9%	20	8.2%	0.789	12	10.9%	7	17.9%	0.271
Disseminated intravascular coagulation, n (%)	43	7.3%	16	6.6%	0.769	11	10.0%	3	7.7%	1.000
Kidney failure, n (%)	11	1.9%	6	2.5%	0.593	9	8.2%	2	5.1%	0.729
CT follow-up/year, median (IQR)	1.62	(1.06–2.57)	2.21	(1.55–3.27)		2.10	(1.20–3.00)	2.40	(1.63–3.11)	

EVAR, endovascular aortic repair; iAAA, intact abdominal aortic aneurysm; OAR, open aortic repair; rAAA, ruptured abdominal aortic aneurysm.

a significantly higher percentage of women (12.5% vs 4.1%, p<0.0001) and a significantly higher median age (62 years vs 65 years, p<0.0001) for EVAR. In the rAAA group, there was no statistically significant difference in the proportion of women between OAR and EVAR, although EVAR had a significantly higher median age (59 years vs 62 years, p<0.0001). There was no statistically significant difference for smoking, one of the prognostic determinants,[1] between OAR and EVAR in either iAAA (40.5% vs 43.0%, p=0.54) or rAAA (36.4% vs 35.9%, p=1.00).

Outcomes

The postoperative outcomes are summarized in table 2. Frequencies of CT follow-up per year (median) were 2.21 (EVAR) and 1.62 (OAR) for iAAA, and 2.40 (EVAR) and 2.10 (OAR) for rAAA.

There were no significant differences in mortality rate and 5-year mortality between OAR and EVAR for either iAAA or rAAA (figure 2).

In rAAA (figure 3B), the reintervention rate was significantly higher in the EVAR group (log-rank p=0.04). The 5-year reintervention ratios for EVAR and OAR were 15.4% and 8.2%, respectively.

In iAAA (figure 3A), there were no group differences in reintervention rates (log-rank p=0.28), where EVAR was lower in the early postoperative period, followed by a gradual increase. The 5-year reintervention ratios for EVAR and OAR were 7.8% and 11.0%, respectively.

Table 3 shows that EVAR (HR 3.07; 95% CI 1.08 to 8.73) was an independent predictor of more frequent reintervention in rAAA after adjusting for baseline variables with multivariate analysis using Cox proportional hazards model.

DISCUSSION

To the best of our knowledge, this is the first RWD study in Japan to evaluate the long-term outcomes of AAA repair using an insurance claims database with anonymous data linkage. Although the 5-year mortality rates of EVAR and OAR were comparable, the higher reintervention rate of EVAR in rAAA suggests that regular follow-up with imaging is critical. International collaborations to create real-world surveillance systems are warranted to overcome minor differences in device use and patient selection with a common goal of improving the quality of care.

The relevance of JMDC, as one of the new sources of RWD, was studied from three different aspects: payment system, anonymous data linkage, and validity of signals. Japanese universal health insurance payment system consists of FFS and DPC.[22] While DRG in the USA is a pay-per-case system, the Japanese DPC is a pay-per-day system with a blanket portion for basic hospital fees and an FFS portion. Therefore, missing data are rare for expensive imaging, surgeries, and devices.[13] The anonymous data linkage system of JMDC enables the evaluation of risk factors and long-term outcomes across hospitals,[19] increasing the sensitivity for reinterventions and CT scans. The validation of signals from the Japanese claims database has been extensively studied. For example, the specificity of codes for procedures, prescriptions, and devices are high, while code combination is needed to compensate for the 'tentative diagnosis' for billing purpose.[23] Therefore, we have used our algorithm[21] for code combination in JMDC to maximize specificity. We have compared our study design, including patient selection and device use (online supplemental table 2) and the short-term and long-term outcomes (online supplemental table 3) with existing registries in Japan.[26–29]

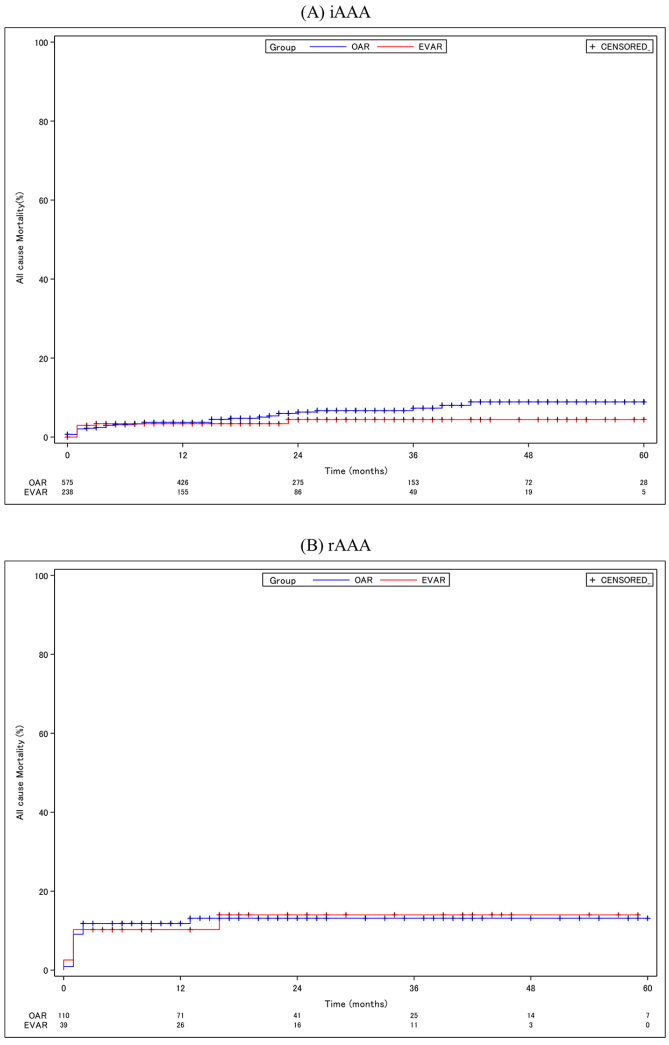

Figure 2 Kaplan-Meier curve and log-rank test for rate of mortality. (A) iAAA (n=837): 30-day mortality (OAR: 2.0% (12/593)), EVAR: 2.9% (7/244)), 5-year mortality (OAR: 5.7% (34/593), EVAR: 3.7% (9/244)), log-rank p=0.326. (B) rAAA (n=149): 30-day mortality (OAR: 9.1% (10/110), EVAR: 10.3% (4/39)), 5-year mortality [OAR: 12.7% (14/110), EVAR: 12.8% [5/39]), log-rank p=0.987. EVAR, endovascular aortic repair; iAAA, intact abdominal aortic aneurysm; rAAA, ruptured abdominal aortic aneurysm; OAR, open aortic repair.

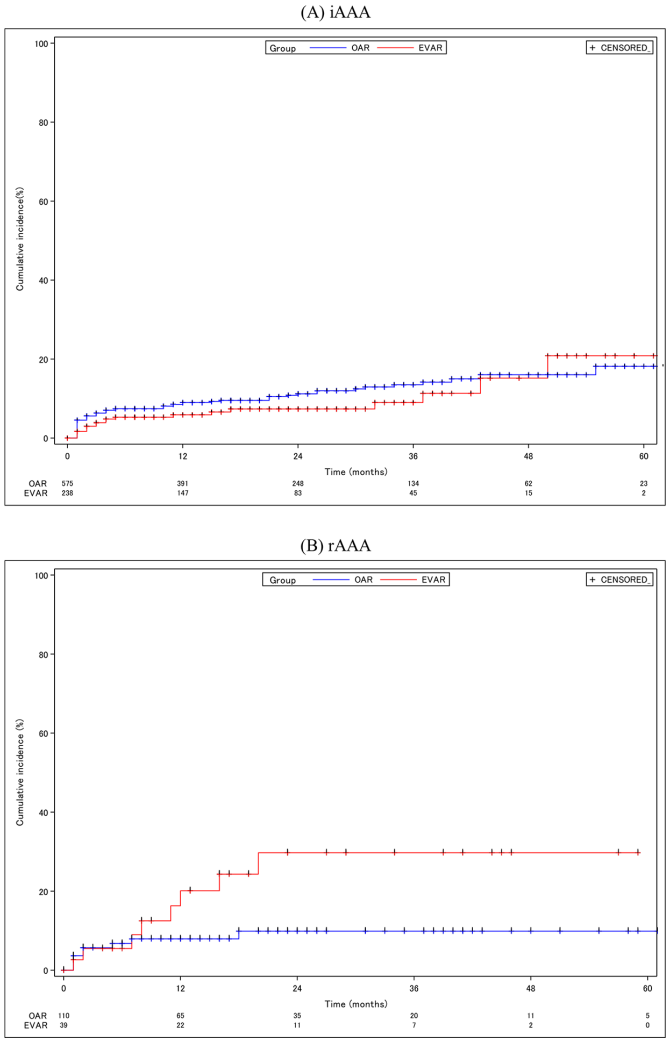

Figure 3 Kaplan-Meier curve and log-rank test for rate of reintervention. (A) iAAA (n=837): event rate (OAR: 11.0% (65/593), EVAR: 7.8% (19/244)), log-rank p=0.284. (B) rAAA (n=149): event rate (OAR: 8.2% (9/110), EVAR: 15.4% (8/39)), log-rank p=0.041. EVAR, endovascular aortic repair; iAAA, intact abdominal aortic aneurysm; rAAA, ruptured abdominal aortic aneurysm; OAR, open aortic repair.

Accordingly, JMDC may have fit-for-purpose quality and relevance to efficiently monitor patients who underwent EVAR, at least for follow-up imaging and reintervention.

Reinterventions to address device or treatment failures are estimated to occur in 20%–30% of EVAR patients.[3 16] We have adopted the definitions of reintervention from claims-based studies in the USA[14–17] and mapped them to fit with the JMDC code (online supplemental table 1). Since existing registries in Japan (online supplemental table 2) did not cover the long-term outcomes of EVAR for rAAA, our report is the first to show that the reintervention rate of EVAR (15.4%) is significantly higher than OAR (8.2%) in rAAA (log-rank p=0.284 (figure 3B)). In addition, the Kaplan-Meier curve indicated that a steady increase canceled the early postoperative advantage of EVAR without a plateau in iAAA (7.8% vs 11.0%, log-rank p=0.284 (figure 3A)). Although EVAR may have a lower perioperative adverse event than OAR, the early advantage may not be maintained long-term. In fact, both sac expansion and no reduction in sac size post-EVAR are associated with endoleaks, which are the most common reason for aortic reinterventions.[30] Therefore, we suggest guidelines recommending lifelong annual follow-up for patients who underwent EVAR starting 30 days post-procedure are relevant, at least for those ≤75 years of age, in Japan.

Follow-up imaging to identify and correct device-related or procedure-related complications after EVAR is recommended by multiple guidelines.[1–5] However, imaging follow-up compliance is reported to be only about 40% despite these important recommendations.[9] Previous reports from Japanese registries did not include information on this critical compliance.[26–29] Because

Table 3 Multivariate Cox proportional hazard analysis adjusting for baseline

	iAAA		rAAA	
	HR	95% CI	HR	95% CI
(A) Five-year mortality				
EVAR (vs OAR)	0.63	0.29 to 1.34	1.35	0.45 to 4.10
Age (years)	1.04	1.00 to 1.08	0.98	0.93 to 1.04
Hypertension	0.63	0.30 to 1.32	1.43	0.50 to 4.12
Dyslipidemia	0.39	0.18 to 0.85	0.82	0.27 to 2.51
Diabetes mellitus	1.36	0.62 to 2.98	0.80	0.17 to 3.79
Chronic heart failure	1.12	0.56 to 2.25	3.57	1.27 to 10.04
Ischemic heart disease	0.83	0.40 to 1.73	0.52	0.20 to 1.37
Atrial fibrillation	1.56	0.70 to 3.49	1.32	0.38 to 4.61
Venous thromboembolism	1.94	1.04 to 3.61	0.37	0.10 to 1.40
History of smoking	0.63	0.32 to 1.23	0.30	0.08 to 1.08
(B) Five-year reintervention				
EVAR (vs OAR)	0.76	0.45 to 1.28	3.07	1.08 to 8.73
Age (years)	1.00	0.98 to 1.03	1.03	0.96 to 1.09
Hypertension	0.91	0.56 to 1.47	0.48	0.16 to 1.47
Dyslipidemia	1.04	0.64 to 1.67	0.89	0.26 to 3.08
Diabetes mellitus	0.94	0.49 to 1.80	0.71	0.15 to 3.32
Chronic heart failure	0.95	0.56 to 1.61	0.64	0.16 to 2.60
Ischemic heart disease	0.88	0.53 to 1.48	2.36	0.74 to 7.52
Atrial fibrillation	1.12	0.58 to 2.18	3.73	1.03 to 13.49
Venous thromboembolism	1.16	0.72 to 1.87	0.08	0.01 to 0.66
History of smoking	0.84	0.54 to 1.31	1.20	0.37 to 3.88

HR and proportional hazard model (multiple variable model) for overall survival (A) and reintervention (B).
Significant p values (p<0.05) are marked.
EVAR, endovascular aortic repair; iAAA, intact abdominal aortic aneurysm; OAR, open aortic repair; rAAA, ruptured abdominal aortic aneurysm.

Japanese hospitals have more CT scanners per capita than other countries,[31] patients may get scanned at a nearby clinic rather than at the tertiary hospital where vascular surgeons belong. The patient-centric nature of JMDC to link procedure codes of follow-up imaging across hospitals has enabled to detection of impressive numbers of CT follow-ups per year (table 2). Therefore, a claims-based database with anonymous linkage can be an example of a relevant and efficient long-term real-world surveillance system to improve care for patients who underwent EVAR.

Mortality is the most critical outcome in long-term follow-up studies. Data from the registry of the JSVS indicated that the 30-day mortality in rAAA (15.7% in OAR and 15.3% in EVAR) was lower than that in Europe (31.6%) and the USA (30.0%).[5 26] Our 30-day and 5-year mortality data after EVAR or OAR were comparable (online supplemental table 3A, 3B). However, while the external validity of claims-based analyses is high for procedures including reintervention and imaging, the patient selection and device use may affect the mortality when using JMDC as a source for RWD. For patient selection in iAAA, guidelines recommend AAA repair for aneurysm sizes larger than 55 mm in males and 50 mm in females.[3–5] However, significant variation exists in the management of AAA,[32 33] and some Japanese hospitals set indications of OAR and EVAR to 50 mm in males and 45 mm in females.[5] Since there is no clinical information available from the JMDC claims database, we have searched the literature and found a detailed analysis from the Japanese Committee for Stent-graft Management (JACSM).[27] The mean diameter was 51 mm (47–57 mm). Of the 37,224 patients who underwent EVAR for iAAA in the JACSM registry, 13,682 (36.8%) were smaller than 50 mm, 10,567 (28.4%) were between 50 and 55 mm, 5256 (14.1%) were between 55 and 60 mm, and 7719 (20.7%) were larger than 60 mm. Therefore, the indication of EVAR for iAAA in the JMDC may also be smaller than in other countries. Regarding the device used for rAAA, the proportion of EVAR (%EVAR) tended to be lower in younger cohorts (online supplemental table 3B), reflecting concerns about the impact of EVAR longevity on long-term outcomes. However, the JACSM registry, collected under the Pharmaceuticals and Medical Devices Act, excluded rAAA cases because of the off-label use. In other words, most of the resource for a

post-marketing surveillance system with the highest sensitivity is not aimed at the highest risk patient population. Therefore, regulators, manufacturers, and academia need to optimize the allocation of resources to create a real-world surveillance system[9] to collect long-term follow-up data for quality improvement.[34–36]

There are opportunities for international collaborations to improve the quality of care.[37] Codes and algorithms from previous claims-based studies helped identify an unmet medical need in Japan, that is, the need to create a real-world surveillance system for the long-term follow-up of EVAR in rAAA. Historically, highly coordinated cooperative efforts of vascular surgeons, such as the VASCUNET and the VQI, have helped develop evidence-based guidelines to improve the outcomes of patients with AAA.[38] In addition, the Medical Device Epidemiology Network (MDEpiNet), a public-private partnership supported by the US FDA, has established the ICVR.[39–41] Japanese surgeons also contributed to internationally coordinated registry networks.[42] One important lesson from the experiences of international collaborations is to have governing structures for data sharing. In addition to direct data sharing from multiple sources, distributed systems enable more inclusive collaboration for research and surveillance. Global efforts have focused on high priority questions related to device use and patient selection variation. From regulatory and industry perspectives, RWE from RWD can be used for pre-market and post-market purposes.[37] However, various factors, including financial incentives, disincentives, varying skillsets, or access to devices, need to be optimized to maximize patient outcomes. Especially, the long-term follow-up linking multiple sources of RWD becomes more challenging when facing data protection laws in different countries. Therefore, further studies on international collaborations to explore feasible and efficient sources of RWD are warranted.

Limitations

This study has some limitations.

First, we could not fully adjust for unmeasured confounding factors in an observational study. Therefore, randomized controlled trials are the gold standard for the appraisal of causalities.

Second, JMDC, like other receipt databases, does not contain medical information such as laboratory data and images. Therefore, known risk factors for AAA, including aortic diameter, may have been confounded. Further studies are needed to clinically validate the sensitivity and specificity of comorbidities and outcomes.

Third, because codes such as UDI, used to uniquely identify devices, are not implemented in the Japanese insurance system, it was impossible to determine the causal relationship between adverse events and specific devices, procedures, or diseases.

Fourth, we studied only those cases that could undergo intervention with EVAR or OAR. However, many cases of rAAA die before surgery or even before arriving at the hospital. Yamaguchi *et al* reported that in octogenarians emergency repair was less likely (42.8% vs 68.0%) but in-hospital death regardless of repair was higher (61.8% vs 37.6%) than in younger patients.[29] Therefore, future studies including older patients are warranted to optimally allocate medical resources and improve the population-based outcomes of rAAA.

Fifth, JMDC is known to have a 'healthy-workers bias'.[21] While the prevalence of AAA is higher in older people, beneficiaries of this claims database JMDC consist of corporate employees and their families aged ≤75 years. Accordingly, age and socioeconomic status may be contributing to lower mortality rates.

Finally, JMDC also has a 'survivorship bias' since the system captures in-hospital deaths directly but out-of-hospital deaths only indirectly. For example, Sakai *et al* reported that although the sensitivity and specificity of procedures, prescriptions, and in-hospital deaths were high, the sensitivity of outpatient death was limited to about 50%.[43] Therefore, although systematic bias between groups is unlikely, our data regarding long-term mortality need to be interpreted with this in mind.

In conclusion, our analysis of the long-term outcomes using a Japanese insurance claims database with anonymous data linkage revealed a high compliance with the regular annual follow-up imaging and comparable 5-year mortality between EVAR and OAR in patients who underwent AAA repair. However, EVAR had a significantly higher reintervention rate in ruptured AAA (rAAA), and a long-term upward trend offset the initial benefit in intact cases (iAAA). Therefore, patients who underwent EVAR should receive lifelong annual follow-up imaging starting at 30 days post-procedure. Furthermore, international collaborations to create real-world surveillance systems are warranted.

Author affiliations
[1]Clinical Pharmacology and Regulatory Science, Juntendo University School of Medicine Graduate School of Medicine, Bunkyo-ku, Japan
[2]Leading Center for the Development and Research of Cancer Medicine, Juntendo University, Bunkyo-ku, Japan
[3]Institute for Medical Regulatory Science, Organization for University Research Initatives, Waseda University, Wakamatsu-cho, Shinjuku-ku, Japan
[4]Department of Public Health, Juntendo University School of Medicine Graduate School of Medicine, Bunkyo-ku, Japan
[5]National Institute of Mental Health, National Center of Neurology and Psychiatry, Kodaira, Japan
[6]Department of Vascular Surgery, Asahikawa Medical University, Midorigaoka higashi Asahikawa, Japan

Twitter Kazuhiro Sase @ksase

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ORCID iDs
Hiroshi Ohtsu http://orcid.org/0000-0003-3261-8828
Kazuhiro Sase http://orcid.org/0000-0002-2714-304X

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