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Editor's Choice – Endovascular Repair Versus Surgical Repair for Japanese Patients With Ruptured Thoracic and Abdominal Aortic Aneurysms: A Nationwide Study

Tetsuo Yamaguchi [a,*], Michikazu Nakai [b], Yoko Sumita [b], Kunihiro Nishimura [b], Junichi Tazaki [c], Ryoichi Kyuragi [d], Yoshihisa Kinoshita [e], Takamichi Miyamoto [a], Yasushi Sakata [f], Toshihiro Nozato [a], Hitoshi Ogino [g]

[a] Department of Cardiology, Japanese Red Cross Musashino Hospital, Tokyo, Japan
[b] The National Cerebral and Cardiovascular Centre, Osaka, Japan
[c] Department of Cardiovascular Medicine, Kyoto University Graduate School of Medicine, Kyoto, Japan
[d] Department of Cardiovascular Surgery, Kyusyu Medical Centre, Fukuoka, Japan
[e] Department of Cardiology, Toyohashi Heart Centre, Toyohashi, Japan
[f] Department of Cardiovascular Medicine, Osaka University Graduate School of, Medicine, Osaka, Japan
[g] Department of Cardiovascular Surgery, Tokyo Medical University, Tokyo, Japan

WHAT THIS PAPER ADDS

This propensity score matched nationwide analysis demonstrated that in hospital outcomes of endovascular repair (ER) were more favourable than those of open surgical repair (OR) for ruptured descending thoracic aortic aneurysms and comparable to those of OR for ruptured abdominal aortic aneurysms (rAAA). Despite a significantly shorter hospital stay, ER showed equivalent good activities of daily living at discharge for both types of aneurysms. To the best of the authors' knowledge, this is the first and largest population based study comparing ER and OR for different types of rAAAs in Japan.

Objective: This study compared outcomes after endovascular aneurysm repair (ER) and open surgical repair (OR) of ruptured descending thoracic aortic aneurysms (rDTAA) and ruptured abdominal aortic aneurysms (rAAA) through a nationwide analysis performed in Japan.

Methods: This was a national registry based retrospective comparative study using data from the Japanese Registry of all Cardiac and Vascular Diseases Diagnostic Procedure Combination (JROAD-DPC) database, a nationwide claim based database from more than 600 hospitals. Patients admitted to certificated teaching hospitals with rDTAA and rAAA and treated by either ER or OR between 1 April 2012 and 31 March 2015 were identified. A propensity score matched analysis was performed to compare ER and OR.

Results: About 40% of the total cohort ($n = 8{,}302$) were managed conservatively for various reasons, including limited options in primary care facilities in certain areas. In total, 983 patients had rDTAA (OR = 511; ER = 472) and 2,320 (OR = 1,754; ER = 566) had rAAA. Altogether, 604 and 1,080 patients were matched with rDTAA and rAAA, respectively. Compared with OR, ER was associated with significantly better in hospital mortality in patients with rDTAA (ER = 22.5%; OR = 29.8% [$p < .001$]) and similar mortality for those with rAAA (ER = 25.7%; OR = 24.3% [$p = .57$]). ER involved significantly shorter hospital stays for rDTAA (ER = 25.5; OR = 32 days [$p < .001$]) and rAAA (ER = 16; OR = 21 days [$p < .001$]). The median Barthel Index at discharge was $\geq$75/100 for all groups, and there were no differences between ER and OR. Total medical costs were significantly lower for ER for rDTAA (ER = ¥6.47 million, OR = ¥7.28 million [$p < .001$]) but were higher for rAAA (ER = ¥4.65 million; OR = ¥3.43 million [$p < .001$]).

Conclusion: A Japanese nationwide observational study showed that in hospital outcomes for ER vs. OR were more favourable for rDTAA and comparable for rAAA. ER resulted in an equivalently favourable functional status at discharge and significantly shorter hospital stays.

Keywords: Endovascular aneurysm repair, Medical cost, Open surgical repair, Propensity score matching, Ruptured abdominal aortic aneurysms, Ruptured descending thoracic aortic aneurysms

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* Corresponding author. Department of Cardiology, Japanese Red Cross Musashino Hospital, 1-26-1 Kyonancho, Musashino 180-8610, Tokyo. Japan.
E-mail address: tetsuo5672@yahoo.co.jp (Tetsuo Yamaguchi).

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INTRODUCTION

Ruptured aortic aneurysms (rAA) are associated with high mortality rates. Peri-operative mortality rates for rAA range from 30% to 50%, even after widespread adoption of endovascular aneurysm repair (ER) for rAA.[1–3] For ruptured abdominal aortic aneurysms (rAAA), ER was associated with 30 day and one year mortality rates that were similar to those of open surgical repair (OR).[4–10] A recent study showed that ER had superior three year mortality rates when performed on anatomically suitable patients.[11] For ruptured descending thoracic aortic aneurysms (rDTAA), some large observational studies showed that ER was associated with better mortality rates than OR;[12–14] however, one failed to show the superiority of ER.[15] The clinical practice guidelines of the European Society for Vascular Surgery recommend ER for both rAAA and rDTAA as the first treatment option when the anatomy is appropriate.[16,17]

The Japanese Registry of all Cardiac and Vascular Diseases (JROAD) database revealed that ER for TAA ($n = 3{,}182$ in 2012, $n = 3{,}935$ in 2013, and $n = 4{,}493$ in 2014; $p_{\text{for trend}} < .001$) and AAA ($n = 6{,}882$ in 2012, $n = 7{,}973$ in 2013, and $n = 9{,}662$ in 2014; $p_{\text{for trend}} < .001$) has been increasing annually in Japan.[18] However, no previous trials have analysed differences in the efficacy of ER for different types of rAAs during the same period or the impact of ER on hospital stay, activities of daily living (ADL) at discharge, and total medical costs. This study compared clinical outcomes after ER and OR for matched cohorts of patients with rDTAA and rAAA in Japan using a large hospital administrative database.

MATERIALS AND METHODS

Database explanation

The data for this study were extracted from the JROAD Diagnostic Procedure Combination (DPC) database, which is a nationwide claims based database with data from Japanese DPC hospitals with beds reserved for cardiovascular reasons. The JROAD-DPC database has been described previously.[19,20] Briefly, almost 60% of DPC hospitals with beds reserved for cardiovascular reasons ($n = 1{,}116$, $n = 1{,}104$, and $n = 1{,}102$ hospitals in 2012, 2013, and 2014, respectively) work with the JROAD-DPC, and all teaching hospitals participated in this study because participation is required for physicians to become certified cardiologists in Japan.[19] There is no selective reporting in the JROAD-DPC database because it is claims based, and hospitals cannot be paid without registering every patient's information. The validity of the DPC database is generally high, especially for primary diagnoses and procedure records.[21]

Study participants

Between 1 April 2012 and 31 March 2015, the JROAD-DPC data were analysed for this study. Identification of patients hospitalised for rAA was based on the International Classification of Diseases (ICD)-10 diagnosis codes related to rAA (rTAA, I71-1; rAAA, I71-3; thoraco-abdominal aneurysm, I71-5). Additionally, the diagnosis written in Japanese was used to increase the accuracy of the diagnosis. Aortic rupture in unspecified locations (I71-8), and patients with ruptured aneurysms from a traumatic cause when this was simultaneously registered as a comorbidity, were excluded. In the JROAD-DPC database, aortic dissections and non-ruptured aortic aneurysms are clearly distinguished from rAAs. Hospitals that did not perform any cardiovascular procedures (including ER) were excluded because of the possibility of patients transferred to such hospitals being dead on arrival. Only patients hospitalised at certified teaching hospitals were included, to standardise the quality of treatment and data.[19,20] Of these patients, those who underwent ER or OR were identified. Patients who underwent both ER and OR were excluded because whether these were intra-operative conversions or planned staged procedure was not determined. In addition, to separate ascending from descending thoracic aneurysms, patients who underwent cardiopulmonary bypass during the same hospital stay were excluded according to a previous study.[14] The following clinical data were extracted from the database: patients' unique identifiers; patients' backgrounds; comorbidities before admission; consciousness level on admission according to the Japan Coma Scale (JCS); treatments performed in the hospital, including operations, drugs, and additional treatments; length of hospital stay; total medical cost; and outcomes including in hospital death and ADL at discharge according to Barthel Index (BI). Diagnosis and comorbidities were primarily defined on the basis of the ICD-10 codes, but they were also checked to examine whether these were compatible with the code data.[19] In the DPC, medical costs were calculated by the sum total of the inclusive components (charges for hospitalisation, examinations, and medication, which have a flat rate per diem fee based on diagnostic categories) plus the fee for service components (charges for expensive procedures such as operations and haemodialysis).[22] The JCS is most widely used for assessing impaired consciousness in Japan.[23,24] In the JCS, a three digit code indicates that the patient cannot be aroused with any forceful mechanical stimuli.[24] In this study, disturbance of consciousness (DOC) was defined as a three digit JCS score (100—300), in accordance with a previous report.[23] The BI is a widely used scale for evaluating ADL by examining the ability to perform 10 basic daily activities, such as walking, eating, bathing, changing clothes, and others, using a 10 point scale.[25] A BI $\geq$ 75/100 indicated favourable ADL ability and was well correlated with favourable modified Rankin scale scores.[26] The primary end point was in hospital mortality; the secondary end points were the BI at discharge, length of hospital stay, and total medical costs.

Ethical considerations

The research plan was approved by the Institutional Review Board of the Japanese Red Cross Musashino Hospital (approval number 367). The requirement for informed

consent was waived because of the anonymised nature of the data. This study was conducted in compliance with the Declaration of Helsinki and Japanese Ethical Guideline for Medical and Health Research involving Human Subjects.

Statistical analysis

Data are expressed as mean ± SD for normally distributed variables and as median (interquartile range [IQR]) for non-normally distributed data. Continuous variables were compared using Student *t* test or the Mann—Whitney *U* test, as appropriate. Categorical data are expressed as *n* (%) and were compared using the chi-square test or Fisher's exact test. A time trend analysis for yearly changes in ER and OR was performed using the Cochran-Armitage trend test. Propensity score (PS) matching was performed to reduce bias caused by differences in patient backgrounds. The PS for each patient was generated using a mixed logistic regression model with the institution as a random intercept constructed with the following variables: age; sex; history of heart failure, cerebrovascular disease, chronic obstructive pulmonary disease, and diabetes mellitus; renal failure on admission (chronic kidney disease class III or higher); transfusion; vasopressor use; and DOC on admission. The adjusted variables used for PS matching did not have any missing data except for age (only two rAAA cases were missing age data). The area under the receiver operating characteristic curve (AUC) was calculated to evaluate the discrimination capability of this PS model. The Hosmer—Lemeshow goodness of fit test was used to examine the calibration of the PS model.[27] PS matching was performed in a one to one manner for patients who underwent ER or OR. Standardised mean differences were calculated to evaluate the quality of the matching. If the standardised differences were <.2, then the two groups were considered well-balanced.[28,29] Subgroup analyses were also performed after PS matching, and the odds ratio and 95% confidence interval (CI) were calculated for each subgroup. The cut off values of the continuous variables in the subgroup analyses were calculated using the receiver operating characteristic curve. The significance of interactions was examined using the Breslow—Day test. Statistical analyses were performed by a physician (T. Yamaguchi) and a statistician (M. Nakai) using Stata 14.2 (Stata, College Station, TX, USA). A two sided $p < .05$ was considered statistically significant.

RESULTS

Patient characteristics

A total of 8,032 patients (age ≥ 20 years) admitted with rAA between 1 April 2012 and 31 March 2015 were potentially eligible for this study. The patient selection flowchart is shown in Fig. 1. A total of 3,516 patients who could not undergo surgical treatment were excluded. Thoraco-abdominal rupture was excluded because the total number of patients with this diagnosis was too small ($n = 186$) for comparison. Four patients with traumatic causes simultaneously registered as comorbidities were also excluded. After excluding non-eligible institutions, the number of hospitals analysed in this study was 610 in 2012, 637 in 2013, and 742 in 2014.

The baseline characteristics of patients treated by ER or OR before and after PS matching are shown in Table S1 (Supplementary Material) and Table 1. Between 2012 and 2014 ER was performed increasingly for both rDTAA (p_{for}

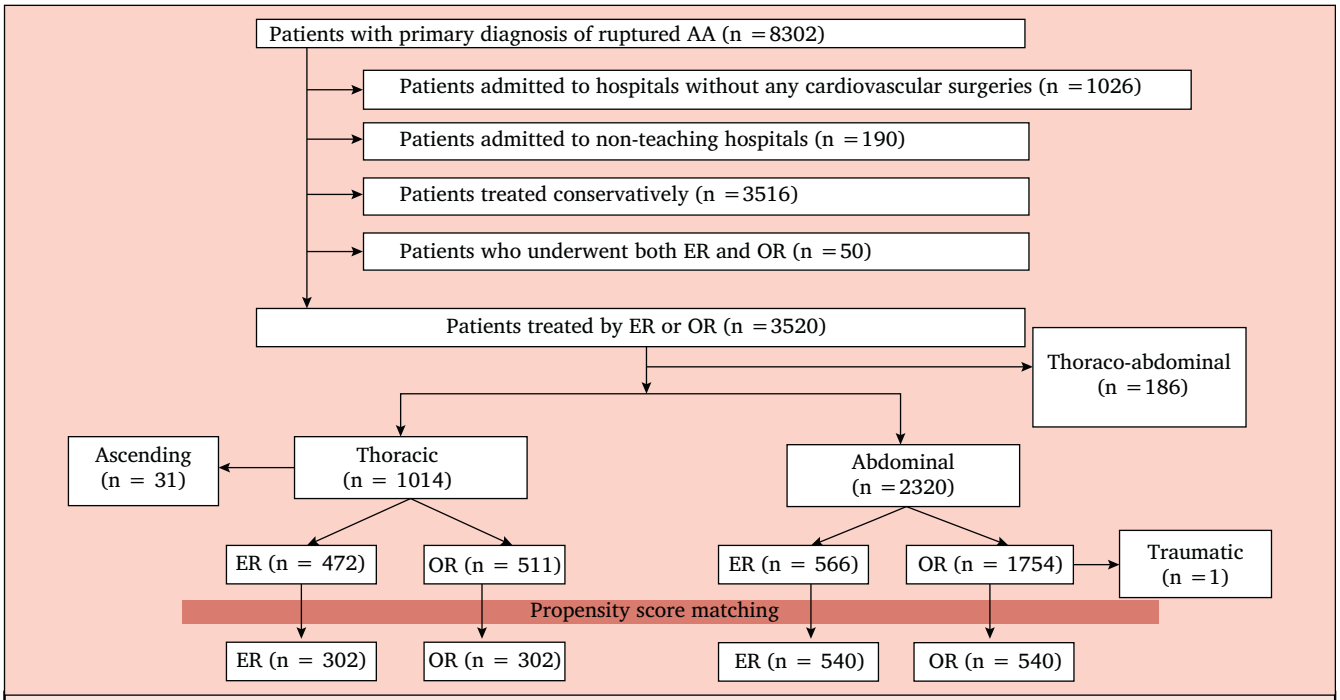

Figure 1. Study flowchart. AA = aortic aneurysm; ER = endovascular repair; OR = open repair.

Table 1. Characteristics of patients in the open surgical repair and endovascular repair groups after propensity score matching

Variables	Descending thoracic				Abdominal			
	OR	ER	*p* value	SMD	OR	ER	*p* value	SMD
Patients (*n*)	302	302			540	540		
Age (y)	76.5 ± 9.1	76.9 ± 9.5	.59	−.04	77.2 ± 9.0	77.5 ± 9.9	.59	−.03
Male sex	219 (72.5)	212 (70.2)	.53	.05	429 (79.4)	407 (75.4)	.11	.10
Body mass index (kg/m^2)	22.7 ± 4.4	22.0 ± 3.8	.05	.17	22.6 ± 4.3	22.6 ± 4.4	.82	.01
Medical history								
Heart failure	41 (13.6)	39 (12.9)	.81	.02	52 (9.6)	65 (12.0)	.20	.08
Myocardial infarction	5 (1.7)	3 (1.0)	.48	.06	15 (2.8)	16 (3.0)	.86	.01
Cerebrovascular disease	20 (6.6)	22 (7.3)	.75	.03	47 (8.7)	48 (8.9)	.910	.001
COPD	13 (4.3)	12 (4.0)	.84	.02	17 (3.1)	21 (3.9)	.51	.04
Diabetes mellitus	34 (11.3)	35 (11.6)	.90	.01	58 (10.7)	63 (11.7)	.63	.03
Cancer	10 (3.3)	19 (6.3)	.09	.14	15 (2.8)	23 (4.3)	.19	.08
Severe complication on arrival								
Renal failure on admission	34 (11.3)	31 (10.3)	.69	.03	48 (8.9)	53 (9.8)	.53	.04
Disturbance of consciousness	16 (5.3)	18 (6.0)	.72	0.03	59 (10.9)	50 (9.3)	.36	.06
Need for additional treatment								
Transfusion	294 (97.4)	299 (99.0)	.13	.12	501 (92.8)	501 (92.8)	1.00	<.001
Vasopressor	287 (95.0)	290 (96.0)	.55	.05	388 (71.9)	390 (72.2)	.89	.008
Hospital size			<.001	.52			.41	.14
20–100 beds	4 (1.3)	5 (1.7)			4 (0.7)	8 (1.5)		
100–200 beds	13 (4.3)	4 (1.3)			9 (1.7)	5 (0.9)		
200–300 beds	38 (12.6)	12 (4.0)			39 (7.2)	28 (5.2)		
300–450 beds	80 (26.5)	50 (16.6)			109 (20.2)	107 (19.8)		
450–750 beds	120 (39.7)	148 (49.0)			266 (49.3)	266 (49.3)		
> 750 beds	47 (15.6)	83 (27.5)			113 (20.9)	126 (23.3)		

Data are *n* (%) or mean ± standard deviation. Disturbance of consciousness was assessed on admission and defined as Japan Coma Scale 100–300. OR = open repair; ER = endovascular repair; SMD = standardised mean difference; COPD = chronic obstructive pulmonary disease.

$_{\text{trend}}$ = .0015) and rAAA ($p_{\text{for trend}}$ < .001). Before PS matching, patients treated by ER were significantly older and had a lower transfusion and vasopressor rate. OR was performed in similar numbers to ER for rDTAA, but by contrast OR was carried out nearly three times more frequently for rAAA. After PS matching, the ER and OR groups were well balanced. The AUC of the PS models were .84 (95% CI 0.81–0.87) for rDTAA and .78 (95% CI 0.75–0.81) for rAAA, and the results of the Hosmer–Lemeshow test were not significant, indicating good discrimination and calibration of the PS models.

Clinical outcomes

Fig. 2 shows the key clinical outcomes of this study. For rDTAA, ER resulted in significantly better in hospital mortality (ER = 22.5%; OR = 29.8% [p = .042]), shorter hospital stays, and lower medical costs (Fig. 2A). For rAAA, ER resulted in significantly shorter hospital stays; however, it failed to show superiority regarding in hospital mortality (ER = 25.7%; OR = 24.3% [p = .57]) and medical costs (Fig. 2B). Despite significantly shorter hospital stays, ER resulted in equivalent BI at discharge for both types of aneurysms, and all four groups showed a median BI ≥ 75/100 at discharge. Table S2 (Supplementary Material) and Table 2 show clinical outcomes of ER and OR for each rupture site before and after matching.

Fig. 3 shows the results of subgroup analyses of rDTAA and rAAA. For rDTAA, the results were significantly modified by age (threshold = 76 years; $p_{\text{interaction}}$ = .006) and DOC on arrival ($p_{\text{interaction}}$ = .023). Older age and DOC on arrival were associated with better outcomes for ER. For rAAA, the results were significantly modified by institutional annual aortic surgery case volume (threshold = 121 aortic operations per year; $p_{\text{interaction}}$ = .030). OR was associated with better outcomes when performed in a hospital with ample aortic surgical experience.

DISCUSSION

This is the first and largest population based, comprehensive study to compare ER and OR for different types of rAAs in Japan. The main finding was that ER was associated with better in hospital outcomes for rDTAA and similar outcomes for rAAA compared with OR. ER resulted in similarly favourable ADL abilities at discharge, despite the significantly shorter hospital stays for both types of rAA. Subgroup analysis results indicated that ER may be suitable for elderly patients with rDTAA. In contrast, OR may be preferable for rAAA, especially when performed in hospitals that have large aortic surgery case volumes.

The number of patients being treated conservatively in this study was higher than the numbers in previous studies comparing ER and OR. This difference could be explained by the fact that hospitals participating in this study were not large referral based surgical centres. In Japan, except for Tokyo and some larger cities, there is no real system for centralisation of patients into designated vascular centres. A certain percentage of patients may be transferred to

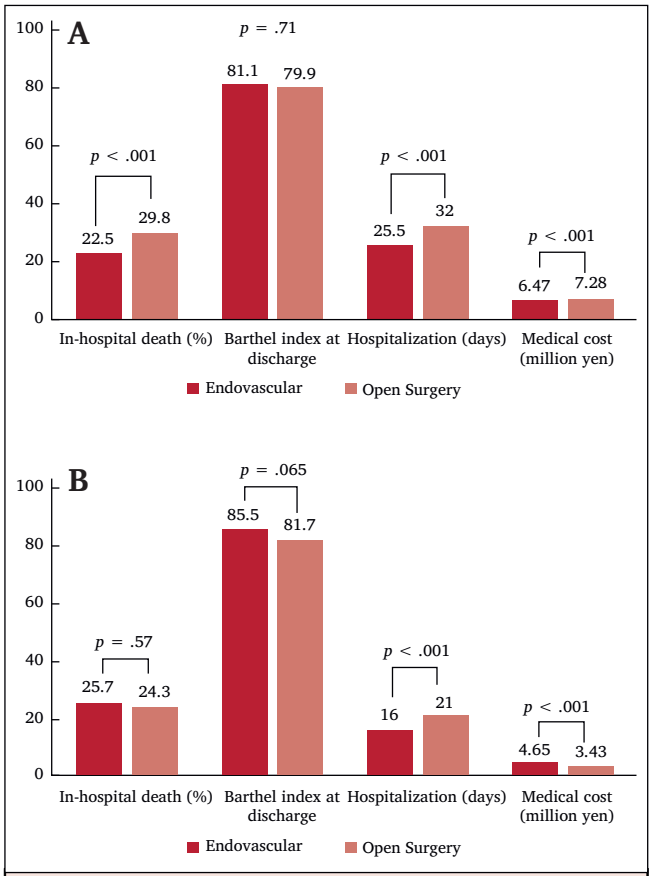

Figure 2. (A) In hospital outcomes for endovascular repair vs. open surgical repair for ruptured descending thoracic aneurysm. (B) In hospital outcomes for endovascular repair vs. open surgical repair for ruptured abdominal aneurysm.

non-referral, non-vascular centres, especially in rural areas. Patients managed conservatively may have comprised those who arrived at hospitals but were likely to die soon after presentation, those who could not undergo surgery because of severe complications, and those whose who were declined surgery. Thus, the results of this study should be interpreted with caution, considering these differences. However, a previous systematic review showed a similar average non-surgery rate of 40%.[30] Considering publication bias, the non-surgery rate at the non-vascular, non-referral centres may be higher. Thus, this high non-surgery rate is considered to be representative of the real world situation in Japan.

In this study, OR was performed nearly three times more often than ER for rAAA, before matching. The proposed reason for this is that, according to Japanese guidelines, national health insurance reimbursement for ER is permitted only for patients at high risk with OR.[31] Other possible reasons were the non-availability of staff trained to perform emergency ER or the unavailability of endografts at some hospitals. The results showed that although the medical cost was higher for ER than for OR, ER was associated with a similar in hospital mortality and ADL ability acquired during significantly shorter hospital stays. Recent studies showed that with the advancement of endografts, approximately 80% of patients with rAAA could be treated by ER,[32] and 75% of these patients could be considered for ER, regardless of their haemodynamic status.[33] In addition, because lower peri-operative morbidity rates and similar in hospital mortality rates with ER have been determined,[4,34,35] ER for rAAA and suitable anatomy could also be recommended as a first line option in Japan,[16] especially for elderly patients with comorbidities.

In contrast to ER for rAAA, ER for rDTAA was performed in similar numbers to OR before PS matching and showed better outcomes than OR. The possible reasons are that Japanese guidelines recommend ER for DTAA for patients at high risk from OR as a first option,[31] and OR for thoracic rAAs usually requires cardiopulmonary supportive devices. Successful completion depends mostly on institutional training, device availability, and the experience of the operators. ER for rDTAA has been used increasingly and appears to be associated with significantly lower peri-operative morbidity and mortality rates than those associated with OR.[12,13,15,36] Therefore, if anatomically applicable, ER for rDTAA may also be the first option in Japan.

In this study, the total length of hospital stay was significantly shorter for ER than OR for both ruptured sites. This result was consistent with that of previous studies.[4,14]

Table 2. Outcomes comparing open surgical repair and endovascular repair for each ruptured site after propensity score matching

Variables	Descending thoracic			Abdominal		
	OR	ER	*p* value	OR	ER	*p* value
Number of patients	302	302		540	540	
In hospital death - n (%)	90 (29.8)	68 (22.5)	.042	131 (24.3)	139 (25.7)	.57
Mean Barthel index ± SD at discharge	79.9 ± 28.5	81.0 ± 27.4	.71	81.7 ± 27.7	85.5 ± 25.2	.065
Median hospital stay (IQR) - d	32 (16–53)	25.5 (15–45)	<.001	21 (13–35.5)	16 (9–26)	<.001
Median medical cost (IQR) - million ¥	7.28 (5.88–9.23)	6.47 (5.00–8.03)	<.001	3.43 (2.63–4.75)	4.65 (3.94–5.75)	<.001

OR = open repair; ER = endovascular repair; IQR = interquartile range; SD = standard deviation.

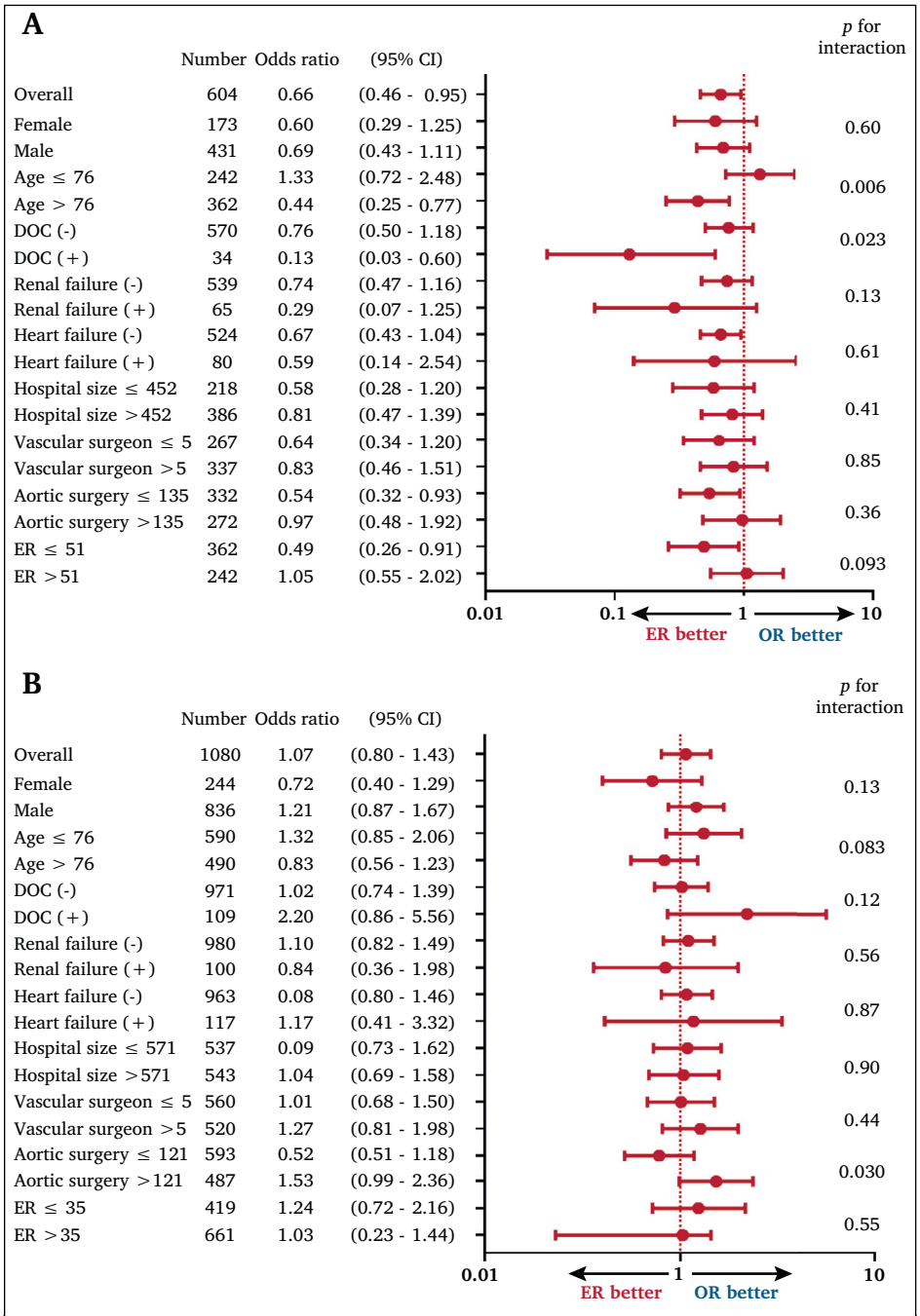

Figure 3. This figure shows odds ratio for in-hospital mortality of two types of treatments (ER vs OR). (A) Subgroup analysis of endovascular repair vs. open surgical repair for ruptured descending thoracic aortic aneurysm. (B) Subgroup analysis of endovascular repair vs. open surgical repair for ruptured abdominal aortic aneurysm. Disturbance of consciousness (DOC) was defined as Japan Coma Scale (JCS) scores between 100 and 300. Aortic surgery was defined as open surgical repair for aortic aneurysm/dissection per year. Endovascular repair (ER) was defined as the number of endovascular aneurysm repairs performed per year. CI = confidence interval; OR = open repair.

However, when compared with the IMPROVE trial, the length of hospital stay for patients with rAAA in this study was much longer (ER = 16 days vs. 9.8 days; OR = 21 days vs. 12.2 days). In addition, medical costs for rAAA were much more expensive in this study compared with the IMPROVE trial (ER = ¥4.65 million vs. ¥2.01 million; OR = ¥3.43 million vs. ¥2.10 million [conversion: £1 = ¥150]. In general, hospital stay is much longer in Japan than in other countries because inpatients generally receive not only acute care, but also nursing care and rehabilitation during a single hospital episode.[37] A longer hospital stay may result in higher medical costs in Japan. In addition, high national health insurance reimbursements for endografts in Japan may be a possible reason for the higher

medical costs for ER, even though length of hospital stay for ER is shorter.

All groups showed a median BI $\geq$ 75/100 at discharge, which indicated favourable ADL at discharge. This could be explained by the longer hospital stays for the purpose of rehabilitation after surgery in Japan. However, ER resulted in equivalent BI at discharge for both types of aneurysms, despite the significantly shorter hospital stay. Therefore, this could be another advantage of ER.

Study limitations

This study had certain limitations. First, because this was a comparative analysis of observational claim based data, there may be a possible risk of misdiagnosis. Selection bias should be considered because of the large number of patients who could not undergo surgery. Although an attempt to adjust for confounders by PS matching, unadjusted confounding factors may have persisted. Second, this database only contains data from the hospitals participating in the JROAD and does not include detailed data such as severity of comorbidities, aortic anatomy and extension, aortic neck length,[38] Fitzgerald classification, type of anaesthesia (local or general), type of endovascular repair (non-complex, fenestrated, or branched), complications such as rupture after chronic dissection or connective tissue disorders in young patients, time from rupture, and actual blood pressure on arrival. Third, reasons for treatment selection could not be found. No data were available to ascertain whether anatomical features were equally distributed between study groups after PS matching. Fourth, although this database has a patient specific identifier for each hospital, data describing the transfer of patients between hospitals prior to surgery are not available. Finally, there was no information regarding the 30 day or longer term mortality or morbidity, which are important determinants of treatment success. However, once discharged alive, patients who underwent ER showed equivalent survival rates at one and five years for thoracic rAA,[35,39,40] and at one year and three years for rAAA.[5,11]

CONCLUSIONS

A PS matched analysis of a Japanese nationwide administrative database demonstrated that the in hospital outcomes of ER were more favourable than those of OR for rDTAA and comparable to those of OR for rAAA. ER resulted in equivalently favourable functional status at discharge and significantly shorter hospital stays.

CONFLICTS OF INTEREST

None.

FUNDING

None.

APPENDIX A. SUPPLEMENTARY DATA

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ejvs.2019.01.027.

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