Ann Vasc Dis Vol. 11, No. 4; 2018; pp 484–489

Online November 22, 2018
doi: 10.3400/avd.oa.18-00099

Original Article

What Did Endovascular Aortic Repair Bring for the Treatment Strategy of Abdominal Aortic Aneurysm?

Hirofumi Midorikawa, MD, PhD,[1] Takashi Takano, MD,[1] Kyohei Ueno, MD,[1] Gaku Takinami, MD,[1] Rie Kageyama, MD,[1] Haruna Seki, MD,[1] Megumu Kanno, MD, PhD,[1] and Kouichi Satou, MD, PhD[2]

Objective: We examined the effects of the introduction of endovascular aortic repair (EVAR) on treatment for abdominal aortic aneurysms (AAAs).

Subjects: We compared patients in the following three periods: period I (January 2002–December 2006, 105 patients), period II (January 2007–December 2011, 242 patients, duration of 5 years after the introduction of EVAR), and period III (January 2012–December 2016, 237 patients, duration of 5 years after period II). We used the American Society of Anesthesiologists (ASA) classification for risk assessment.

Results: In the Open repair (OR) group, the incidences of ASA class 2 increased and classes 3 and 4 decreased significantly in periods II and III compared with period I. In all periods, there were no in-hospital deaths. Suprarenal aortic cross-clamping was required in 18 patients (19.1%) in period III and 5 patients (6.3) in period I, and the difference was significant ($P<0.05$). In the EVAR group, no differences in age, sex, or ASA classification class were observed between periods II and III. In period II, one patient died due to aneurysm rupture during surgery. Significant differences were observed when comparing both groups in periods II and III: patients in the EVAR group were older ($P<0.01$) and the OR group had a higher proportion of ASA class 2 patients and the EVAR group had a higher proportion of ASA class 3 or 4 patients ($P<0.01$). Among all AAA surgeries, rupture occurred in 25 patients (23.8%) in period I, 18 patients (7.4) in period II, and 16 patients (6.8) in period III. The number of ruptures was significantly lower in periods II and III than in period I ($P<0.01$).

Conclusions: The findings of this study suggest that EVAR should be indicated for high-risk patients and had the good outcome of AAA treatment. (This is a translation of Jpn J Vasc Surg 2018; 27: 27–32.)

Keywords: abdominal aortic aneurysm, endovascular aortic repair, open repair

[1] *Department of Cardiovascular Surgery, Southern TOHOKU General Hospital, Koriyama, Fukushima, Japan*
[2] *Department of Cardiovascular Surgery, Sukagawa Hospital, Sukagawa, Fukushima, Japan*

Received: September 5, 2018; Accepted: September 5, 2018
Corresponding author: Hirofumi Midorikawa, MD, PhD. Department of Cardiovascular Surgery, Southern TOHOKU General Hospital, 7-115 Yatsuyamada, Koriyama, Fukushima 963-8563, Japan
Tel: +81-24-934-5322, Fax: +81-24-922-5320
E-mail: hm0527@mt.strins.or.jp
This is a translation of Jpn J Vasc Surg 2018; 27: 27–32.

Introduction

In prospective randomized controlled trials[1,2] of therapeutic outcomes of endovascular aneurysm repair (EVAR) and conventional open repair (OR) for abdominal aortic aneurysm (AAA) conducted in the West in 2005, good early-to-midterm outcomes of EVAR were reported. In Japan, after EVAR was included under the national health insurance coverage in 2007, many institutions performed it primarily for patients in whom OR was associated with high risk; however, it is now an indispensable therapeutic procedure for AAA. On the other hand, with regard to the long-term outcomes based on the rupture avoidance rate, EVAR is considered inferior to OR.[3] Thus, although EVAR is an effective treatment for AAA, several studies have examined the type of patients for whom EVAR should be indicated to improve treatment outcomes.[4–8] In the present study, we retrospectively examined the contribution of EVAR to AAA treatment strategy at our institute.

Subjects and Methods

The study duration was divided into three periods: period I, 5 years prior to EVAR introduction at our hospital (January 2002–December 2006); period II, 5 years after its introduction (January 2007–December 2011); and period III, subsequent 5 years (January 2012–December 2016). Among the 584 patients, the OR:EVAR ratio was 105:0 patients in period I, 101:141 in period II, and 100:137 in period III. Rupture of AAA (RAAA) was observed in 59 patients (**Fig. 1**). Pre- and intraoperative factors with early

outcomes were compared for each surgical procedure and period, while OR and EVAR were compared for each period. Furthermore, the instructions for use (IFU) and incidence of endoleaks in EVAR were evaluated. Statistical analyses were performed using the Student's t-test and Chi-squared test. $P<0.05$ was considered statistically significant. Risk evaluation was performed using the American Society of Anesthesiologists (ASA).

There were some changes according to period; however, we outlined the basic elective AAA treatment strategy of our hospital. EVAR is indicated for patients aged >75 years and when anatomical requirements are met. When the anatomical requirements are not met, OR is selected if it can be endured by the patient; then, if OR is deemed as high-risk, follow-up observation is performed. OR is the first choice of treatment for patients aged <75 years if the procedure can be endured; EVAR is selected if the OR procedure is considered highly risky and the anatomical requirements are satisfied. At our hospital, EVAR is essentially indicated in case of anatomical indications, including device selection, and for patients aged >75 years in whom OR is thought to carry high risk, such as those with cerebrovascular disease, ischemic heart disease, chronic obstructive pulmonary disease, renal dysfunction, cancer, and history of laparotomy (in particular, patients with a colostomy or vesical fistula in whom it is technically difficult to open not only the abdominal cavity but also the retroperitoneum by OR).

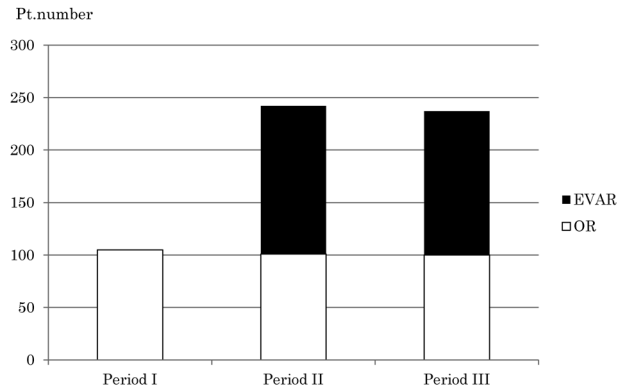

Fig. 1 AAA patients number.

Results

OR elective surgery

For the overall study duration, there were no significant differences in the age and sex among the periods; however, patients in periods II and III tended to be younger than those in period I. In the ASA classification, the rate of occurrence of ASA class 2 was significantly higher in periods II and III than in period I ($P<0.01$), whereas that of class 3 was lower ($P<0.05$). The number of patients with ASA class 4 was significantly lower in period III than in periods I and II ($P<0.01$). Suprarenal artery clamping increased from five patients in period I (6.3%) to 13 in period II (15.5%) and 18 in period III (19.1%), with a statistically significant increase observed in period III compared with period I ($P<0.05$). Throughout the study duration, no hospital deaths were observed (**Table 1**).

EVAR elective surgery

In periods II and III, no differences in age, sex, and ASA classification were observed. The main devices used included the Excluder (W.L. Gore and Association, Flagstaff, AZ, USA) and Zenith devices (Cook Medical, Bloomington, IN, USA) in period II and Excluder (including C3) and Endurant devices (including II) (Medtronic Cardiovascular, Santa Rosa, CA, USA) in period III. IFU slightly differed depending on the device. However, considering the location (proximal and distal to the neck) and approach, EVAR was performed outside the recommended IFU when the proximal neck was large or small, flexion was ≥60°, and landing zone length was ≤15 mm; when the distal neck was large or small, landing zone length was ≤10 mm, and in case of bilateral common iliac artery aneurysm (unilateral internal iliac artery preservation not possible); and when device insertion was difficult for the approach route (flexion, stricture, or occlusion). In period II, EVAR was performed outside IFU in 16 patients

Table 1 Pre and postoperative risk factors and results for elective open repair cases

	Period I	Period II	Period III	P value
Age	73.4±30.7	68.3±10.6	66.4±7.6	NS
Gender				
Male : Female	75 : 5	71 : 13	80 : 14	NS
ASA classification				
Class 2	30 (37.5%)	51 (60.7%)**	76 (80.9%)**	**P<0.01
Class 3	35 (43.8%)	20 (23.8%)*	14 (14.9%)*	*P<0.05
Class 4	15 (18.7%)	13 (15.5%)	4 (4.2%)**	**P<0.01
Suprarenal renal clamp	5 (6.3%)	13 (15.5%)	18 (19.1%)**	**P<0.01
Hospital mortality	0 (0%)	0 (0%)	0 (0%)	

(11.4%) for proximal neck factors, four (2.9%) for distal neck factors, and 11 (7.9%) for approach factors, whereas in period III, the corresponding data were 13 (10.2%), five (3.9%), and 11 (8.7%), respectively, with no statistically significant differences between the two periods. EVAR was performed outside IFU in approximately 20% of the cases. Furthermore, in the evaluation of endoleaks by contrast-enhanced computed tomography at 1 week postoperatively, we found type 1a in five patients (3.6%), type 1b in one (0.7%), type 2 in 23 (16.4%), and type 3 in two (1.4%) in period II. On the contrary, we found type 1a in one patient (0.8%), type 1b in one (0.8%), and type 2 in 16 (12.6%) in period III, with no statistically significant differences between the two periods; however, in period III, there were fewer type 1 and 2 endoleaks. In period II, one patient was lost due to intraoperative RAAA (**Table 2**).

Table 2 Pre and postoperative risk factors and results for elective endovascular aortic repair cases

	Period II	Period III	P value
Age	74.0±6.3	74.5±6.7	NS
Gender			
Male : Female	122 : 18	110 : 17	NS
ASA classification			
Class 2	51 (36.4%)	37 (29.1%)	NS
Class 3	74 (52.9%)	72 (56.7%)	NS
Class 4	15 (10.7%)	18 (14.2%)	NS
Device			
Zenith or Flex	37 (26.4%)	2 (1.6%)	
Powerlink	9 (6.4%)	—	
Excluder or C3	94 (67.2%)	82 (64.6%)	
Endurant I or II	—	43 (33.8%)	
Outside the IFU		—	
Proximal	16 (11.4%)	13 (10.2%)	NS
Distal	4 (2.9%)	5 (3.9%)	NS
Approach	11 (7.9%)	11 (8.7%)	NS
Endoleak			
Type 1a	5 (3.6%)	1 (0.8%)	NS
1b	1 (0.7%)	1 (0.8%)	NS
Type 2	23 (16.4%)	16 (12.6%)	NS
Type 3	2 (1.4%)	—	NS
Hospital mortality	1 (0.7%)	0 (0%)	NS

Comparison of OR and EVAR elective surgeries

There was no difference in sex between periods II and III; however, the EVAR group was older in both periods II and III, and in particular, the EVAR group was significantly older in period III ($P<0.01$). For periods II and III, the OR group had significantly more number of patients with ASA class 2 ($P<0.05$ and $P<0.01$, respectively), whereas the EVAR group had more number of patients with class 3 ($P<0.01$). In period III, the EVAR group had significantly more number of patients with ASA class 4 ($P<0.05$; **Table 3**).

RAAA transition

Overall, RAAA for AAA surgery occurred in 25 patients in period I (23.8%, OR/EVAR: 25/0, hospital deaths: 5 [20%]), 18 in period II (7.4%, 17/1, 3 [16.7%]), and 16 in

Table 3 Preoperative risk factors for elective cases between open repair and endovascular aortic repair

	Period II OR/EVAR	Period III OR/EVAR	P value
Age	68.3±10.6/74.0±6.3	66.4±7.6/74.5±6.7**	**P<0.01
Gender			
Male : Female	71 : 13/122 : 18	80 : 14/110 : 14	NS
ASA classification			
Class 2	51 (60.7%)/51 (36.4%)*	76 (80.9%)/37 (29.1%)**	*P<0.05 **P<0.01
Class 3	20 (23.8%)/74 (52.9%)**	14 (14.9%)/72 (56.7%)**	**P<0.01
Class 4	13 (15.5%)/15 (10.7%)	4 (4.2%)/18 (14.2%)*	*P<0.05

Table 4 The change and clinical results of ruptured abdominal aortic aneurysm cases

	Period I	Period II	Period III	P value
Total number	105	242	237	
Ruptured number	25 (23.8%)	18 (7.4%)**	16 (6.8%)**	**P<0.01
Procedures				
OR/EVAR	25/0	17/1	6/10	
Hospital mortality				
OR/EVAR	5 (20%)/0	3 (16.7%)/0	2 (12.5%)/2 (12.5%)	

period III (6.8%, 6/10, 4 [25%]), indicating significantly lesser RAAA occurrence in periods II and III than in period I ($P<0.01$). In addition, the indication for EVAR considerably increased from one patient in period II (5.6%) to 10 in period III (62.5%; **Table 4**).

Discussion

Good initial outcomes in the EVAR trial 1[1] and Dream trial,[2] which were prospective randomized controlled trials for OR and EVAR, increased the importance of EVAR for the treatment of AAA. In addition, in Japan, EVAR was covered under the national health insurance in 2007 and is now indispensable for the treatment of AAA. However, in Japan, the Ministry of Health, Labor, and Welfare issued a notice recommending the clinical application of EVAR in patients in whom conventional OR has high risk and who meet the anatomical indications for EVAR. On the other hand, with advancements in stent placement techniques and devices, there has been an increase in the number of patients who do not strictly satisfy IFU.[9] Furthermore, regarding long-term outcomes (at 8 years postoperatively), the rate of rupture was significantly higher in the EVAR group than in the OR group.[3] Considering the good long-term outcomes for OR,[10] we believe that there may be a period when the indication of EVAR may have to be reconsidered.

At our institute, since the introduction of commercialized EVAR devices in 2007, we have gained >10 years of experience in their usage and accumulated patients for whom these devices were used. We divided our experience into three periods as follows: period I, 5 years prior to EVAR introduction (January 2002–December 2006); period II, 5 years after its introduction (January 2007–December 2011); and period III, subsequent 5 years (January 2012–December 2016). We attempted to retrospectively examine the effects of the introduction of EVAR on AAA treatment strategy and the appropriate clinical application of EVAR.

The effectiveness of EVAR for elderly patients and those with many risk factors and the use of ASA classification for preoperative risk evaluation have been reported.[4,5,8] The effectiveness of EVAR for high-risk patients who are unsuitable for OR has also been reported.[11] Furthermore, some reports have described that AAA treatment for high-risk and elderly patients are being switched to EVAR.[8,12] In our patients, we found that the introduction of EVAR reduced the age of patients who underwent OR, increased the number of those with ASA class 2, and decreased the number of those with ASA class 3 or 4. On the other hand, there were more elderly patients and those with ASA class 3 or 4 in the EVAR group than in the OR group, resulting in fewer patients at a risk of OR. Furthermore, there were more high-risk patients for whom EVAR was indicated. Based on these results, from period I when OR alone was performed to periods II and III after the introduction of EVAR, the number of patients who underwent surgeries, including those at high risk, increased by >2-fold, thereby resulting in extremely good outcomes, as indicated by only one hospital death (0.2%) associated with elective AAA surgery during the 15-year period.

Given the device properties, anatomical indications are stipulated for EVAR, and in particular, the proximal neck poses a major problem; hence, the reported initial and midterm outcomes have been poor in case of EVAR performed outside the recommended IFU.[13] The criteria for challenging proximal neck (CPN) are defined as follows: 1) diameter ≥28 mm, 2) length <15 mm, 3) angle ≥60°, 4) reverse tapered or bulging, and 5) mural thrombosis ≥50%; unless OR carries a high risk with these criteria, it should be the first choice of treatment.[14] In our patients, there was no difference in the number of patients with CPN who underwent EVAR in periods II and III; however, fewer type 1a endoleaks were observed. We believe that this is attributable to device improvement, such as with the Excluder C3 and Endurant II, and an increase in the number of OR performed in period III for patients with CPN in whom EVAR is difficult to perform. Therefore, at present, OR should be selected for low-risk CPN; however, future improvements in devices will further expand the indications of EVAR.

Moreover, the most interesting question raised is how EVAR introduction affected the treatment outcomes of AAA. Giles et al.[15] reported that the introduction of EVAR increased the number of treatments for patients with unruptured aneurysm and decreased RAAA cases. Moreover, Hill et al.[16] reported that one-third of AAA cases were treated at high-volume centers in which treatment tends to shift to EVAR, and this shift may be responsible for the decrease in the overall mortality of AAA to 23%. Furthermore, Handa et al.[17] reported that the introduction of EVAR did not increase the mortality rate, expanded the indications of AAA treatment, and reduced the risk of general anesthesia and emergency surgery. In our study, the number of patients who underwent OR was comparable throughout the three periods over 15 years, whereas the number of patients who underwent EVAR considerably increased relative to AAA, which can be attributed to the increased indications for patients in whom conventional OR was deemed to be high-risk and who were considered unable to undergo surgery. Furthermore, increased indications of EVAR reduced the number of untreated AAA patients, which may have reduced RAAA occurrence. Furthermore, good outcomes of EVAR for RAAA have been reported,[18] and in our patients, the clinical application is increasing and is expected to improve

the treatment outcomes.

In future, to improve the clinical outcomes of EVAR, it is important to address the challenge of treating endoleaks. In general, for types 1 and 3, unless intra-aneurysmal pressure is reduced, there is a high risk for aneurysm rupture; therefore, therapeutic intervention is necessary. However, for type 2, the timing and stage for intervention remain controversial.[19,20] In the present study, rupture complications occurred in 16.4% of patients in period II and 12.6% in period III. Kichikawa et al.[20] reported that compared with pretreatment, patients with enlargement of >10 mm or 5 mm in 6 months should receive therapeutic intervention, while Thimaran et al.[21] reported that for AAAs, if the diameter of the endoleak on contrast-enhanced CT is >15 mm, there is a high risk of aneurysm enlargement. We also decide retreatment intervention based on the above factors; however, we believe that clear criteria to determine intervention have not been evaluated, and that further examination is needed based on long-term outcomes.

In the present study, expanding the indication of EVAR for high-risk patients reduced the risk of OR, and compared to period I in which OR alone was performed, the number of patients increased by >2-fold after the introduction of EVAR in periods II and III. Moreover, we successfully achieved stable clinical outcomes. The present study was a single-center retrospective study, and considering that we only examined the trend in clinical outcomes and treatment selection at the institution, conducting a multi-center study in Japan in future will help in appropriate indication for OR and EVAR for the treatment of AAA, which will in turn help in improving the treatment outcomes.

Conclusion

The introduction of EVAR markedly increased the number of patients with AAA undergoing surgeries. High-risk patients tended to undergo EVAR, and while the risk of OR was reduced, there was an increase in the number of patients in whom the level of technical difficulty was high, such as those with AAA of the pararenal artery or renal artery, and the indication of EVAR was difficult. Furthermore, there were fewer patients with RAAA. We believe that the introduction of EVAR is an indispensable treatment method to achieve stable treatment outcomes for AAA.

Disclosure Statement

All authors have no conflicts of interest to declare.

References

1) Greenhalgh RM, Brown LC, Kwong GP, et al. EVAR trial participants. Endovascular aneurysm repair versus open repair in patients with abdominal aortic aneurysm (EVAR trial 1): randomised controlled trial. Lancet 2005; **365**: 2179-86.
2) Blankensteijn JD, de Jong SECA, Prinssen M, et al. Two-year outcomes after conventional or endovascular repair of abdominal aortic aneurysms. N Engl J Med 2005; **352**: 2398-405.
3) Patel R, Sweeting MJ, Powell JT, et al. Endovascular versus open repair of abdominal aortic aneurysm in 15 years' follow-up of the UK endovascular aneurysm repair trial 1 (EVAR trial 1): a randomised controlled trial. Lancet 2016; **388**: 2366-74.
4) Chuter TAM, Reilly LM, Faruqi RM, et al. Endovascular aneurysm repair in high-risk patients. J Vasc Surg 2000; **31**: 122-33.
5) Jackson RS, Chang DC, Freischlag JA. Comparison of long-term survival after open vs endovascular repair of intact abdominal aortic aneurysm among medicare beneficiaries. JAMA 2012; **307**: 1621-8.
6) Chadi SA, Rowe BW, Vogt KN, et al. Trends in management of abdominal aortic aneurysms. J Vasc Surg 2012; **55**: 924-8.
7) Nathan DP, Brinster CJ, Jackson BM, et al. Predictors of decreased short- and long-term survival following open abdominal aortic aneurysm repair. J Vasc Surg 2011; **54**: 1237-43.
8) Dias NV, Ivancev K, Malina M, et al. Does the wide application of endovascular AAA repair affect the results of open surgery? Eur J Vasc Endovasc Surg 2003; **26**: 188-94.
9) Nishina T, Nakatsuka D, Hori Y, et al. Open repair after EVAR introduction for abdominal aortic aneurysm. Japanese Journal of Vascular Surgery 2013; **22**: 791-6. (in Japanese)
10) Dardik A, Lin JW, Gordon TA, et al. Results of elective abdominal aortic aneurysm repair in the 1990s: a population-based analysis of 2335 cases. J Vasc Surg 1999; **30**: 985-95.
11) Lim S, Halandras PM, Park T, et al. Outcomes of endovascular abdominal aortic aneurysm repair in high-risk patients. J Vasc Surg 2015; **61**: 862-8.
12) Chadi SA, Rowe BW, Vogt KN, et al. Trends in management of abdominal aortic aneurysms. J Vasc Surg 2012; **55**: 924-8.
13) Best WB, Ahanchi SS, Larion S, et al. Abdominal aortic aneurysm anatomic severity grading score predicts implant-related complications, systemic complications, and mortality. J Vasc Surg 2016; **63**: 577-84.
14) Chisci E, Kristmundsson T, de Donato G, et al. The AAA with a challenging neck: outcome of open versus endovascular repair with standard and fenestrated stent-grafts. J Endovasc Ther 2009; **16**: 137-46.
15) Giles KA, Pomposelli F, Hamdan A, et al. Decrease in total aneurysm-related deaths in the era of endovascular repair. J Vasc Surg 2009; **49**: 543-50; discussion, 550-1.
16) Hill JS, McPhee JT, Messina LM, et al. Regionalization of abdominal aortic aneurysm repair: evidence of shift to high-volume centers in the endovascular era. J Vasc Surg 2008; **48**: 29-36.
17) Handa N, Yamashita M, Takahashi T, et al. Impact of intro-

ducing endovascular aneurysm repair on treatment strategy for repair of abdominal aortic aneurysm: National Hospital Organization Network study in Japan. Circ J 2014; **78**: 1104-11.
18) Edwards ST, Schermerhorn ML, O'Malley AJ, et al. Comparative effectiveness of endovascular versus open repair of ruptured abdominal aortic aneurysm in the Medicare population. J Vasc Surg 2014; **59**: 575-82.
19) Lo RC, Buck DB, Herrmann J, et al. Risk factors and consequences of persistent type II endoleaks. J Vasc Surg 2016; **63**: 895-901.
20) Kichikawa K, Iwakoshi S, Ito H, et al. Diagnosis and treatment of endoleak after thoracic endovascular aortic repair or endovascular aortic repair. Journal of the Japanese Surgical Society 2014; **115**: 84-9. (in Japanese)
21) Timaran CH, Ohki T, Rhee SJ, et al. Predicting aneurysm enlargement in patients with persistent type II endoleak. J Vasc Surg 2004; **39**: 1157-62.