**Original
Article**

Risk Factors in the Treatment of Abdominal Aortic Aneurysms in the Endovascular ERA

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Purpose: Endovascular aneurysm repair (EVAR) is a minimally invasive treatment that is becoming standard in abdominal aortic aneurysm treatment. We examine the risk factors of death by comparing the short-term results of abdominal aortic aneurysm by open surgical repair with EVAR.

Methods: We performed elective abdominal aortic aneurysm treatment on 122 cases during the period from January 2008 to December 2009. Seventy one cases were treated with open surgical repair while 51 cases were treated with EVAR.

Results: Compared to the open surgical repair group, the EVAR group was significantly older and had a higher complication rate and past laparotomy rates. No significant difference in hospital deaths was observed between the two groups. Two deaths with thromboembolism due to shaggy aorta were observed in the EVAR group. Two cases in the open surgical repair group developed postoperative myocardial infarction and one death was observed. Both patients underwent coronary artery treatment using drug eluting stents (DES) prior to surgery.

Conclusion: Shaggy aorta has a high possibility of causing thromboembolism and EVAR should not be performed unless there is a considerable reason. In cases in which coronary artery treatment is performed with DES in recent days, EVAR is more preferable.

Keywords: abdominal aortic aneurysm, EVAR, stent graft

Introduction

Advantageous short-term results for endovascular aneurysm repair (EVAR) were reported over many tri-

als,^{1,2)} however, a high retreatment rate and medical cost problems have also been indicated.^{3,4)} It is true that fatal complications have been declining significantly with abdominal aortic aneurysm treatment due to the spread of EVAR. Nevertheless, the mortality rate of open surgical repair mentioned in reports in foreign countries seems to be higher than the mortality rate of open surgical repair in Japan.^{5,6)} We compared EVAR and open surgical repair at a single facility (Kawasaki-Saiwai Hospital), compared preoperative factors and postoperative complications, and examined postoperative acute phase complications of the EVAR era.

Materials and Methods

The perioperative outcomes of 122 patients undergoing elective operations (open surgical repair in 71

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patients; EVAR in 51 patients) between January 2008 and December 2009 at Kawasaki-Saiwai Hospital were retrospectively evaluated. The age, gender, diameter of the aortic aneurysm, and morphology of the aortic aneurysm were examined as preoperative state factors. The serum creatinine (Cr) level, cardiac comorbidities, respiratory comorbidities, and history of laparotomy were used for evaluation of preoperative comorbidities. Cardiac comorbidities were defined as electrocardiographic findings of ischemia, a history of myocardial infarction, effort angina, a history of treatment for coronary artery disease, significant stenosis indicated by coronary angiography, congestive heart failure, or $\leq 40\%$ of the left ventricular ejection fraction (LVEF) on ultrasound cardiography. Respiratory comorbidities were defined as being under treatment for respiratory disease, or chronic obstructive pulmonary disease (COPD). Simple appendectomy and laparoscopic cholecystectomy were not included in the history of laparotomy.

A comparison and analysis were made considering the length of the operation, postoperative hospitalization, and the incidence of in-hospital death as perioperative outcome factors, and of the incidence of cerebral infarction, myocardial infarction, ischemic enteritis, thrombosis of the superior mesenteric artery, lower limb ischemia, and wound infection were compared and examined as complication factors. In addition, the presence or absence of endoleaks and the type of endoleak in contrast computed tomography (CT) examinations routinely performed about a week after the procedure prior to discharge were examined with regard to endoleak complications specific to EVAR.

Statistical analysis

The continuous variables are expressed as the means $\pm$ standard deviation. Comparisons between continuous variables were performed using a one-way analysis of variance (ANOVA), and the categorical variables were compared by the chi-square test. A $P < 0.05$ was considered to be statically significant. All statistical analyses were performed using the commercial statistical SPSS version 15.0 software program for windows (SPSS, Chicago, Illinois, USA).

Results

The characteristics of patients in the preoperative state (Table 1)

The two groups showed no significant differences in

gender, but the EVAR group had a significantly higher mean age and a smaller diameter of aortic aneurysm. Open surgical repair was performed in all cases for aortic dissections, while EVAR was used for saccular aneurysms. With regard to the preoperative comorbidities, the two groups showed no significant differences in the serum Cr level and prevalence rate of respiratory comorbidities, however, the EVAR group had significantly higher rates of cardiac comorbidities and history of laparotomy.

Intra-operative procedures (Table 2)

In the EVAR group, treatment in the IFU (instructions for use) range was performed for 37 patients (72.5%). The equipment used was the Zenith device (Cook, Copenhagen, Denmark) for 35 patients (68.6%), the Excluder (W. L. Gore & Associates, Flagstaff, Arizona, USA) for 11 patients (21.6%), the PowerLink (Endologix, Irvine, California, USA) for four patients (7.8%), and a homemade device used for one patient (2.0%). Procedures performed simultaneously with EVAR included embolization of the internal iliac artery in 20 patients (39.2%), and the placing of a large Palmaz stent at the proximal neck for seven patients (13.7%). The grafts used in open surgical repair were tube grafts for 47 patients (66.2%), and bifurcated grafts for 24 patients (33.8%). The EVAR group had a significantly lower intra-operative blood loss and transfusion rate.

The perioperative outcomes of the patients (Table 3)

The mean length of surgery in the EVAR group was 131 minutes, which was significantly shorter than that of the open surgical repair group, which was 155 minutes. The mean postoperative hospitalization was 8.7 days in the EVAR group and 16.4 days in the open surgical repair group, meaning that patients in the EVAR group could be discharged significantly earlier. In-hospital death occurred in two patients (3.9%) in the EVAR group and one patient (1.4%) in the open surgical repair group, which was not significantly different. The two patients who died in the EVAR group were complicated octogenarians with shaggy aorta. Cholesterol crystal embolization with eosinophilia was occurred in both the patients. The causes of death were mesenteric infarction and revascularization syndrome after lower limb ischemia. Although, EVAR is unapproved to use in patients with shaggy aorta, we had no other choice due to their physical conditions.

None of the perioperative complications examined were significantly different between the two groups. Cerebral infarction, ischemic colitis, and lower limb ischemia

Table 1 Baseline characteristics

Preoperative variables	EVAR (n = 51)	Open repair (n = 71)	P value
Age (years)	74.4 ± 8.1 (r. 62 – 91)	69.7 ± 9.4 (r. 37 – 87)	0.14
Male gender	46 (90.2%)	60 (84.5 %)	0.424
Max diameter (mm)	46.6 ± 10.5	52.9 ± 8.0	0.001
Aortic dissection	0 (0%)	10 (14.1%)	0.005
Saccular	9 (17.6%)	0 (%)	0
Serum creatinine level (mg/dl)	1.24 ± 1.31	1.16 ± 1.04	0.872
Cardiac co-morbidity	30 (58.8%)	21 (29.6%)	0.002
Pulmonary co-morbidity	19 (37.3%)	20 (28.2%)	0.328
History of abdominal surgery	21 (41.2%)	14 (19.7%)	0.014

Table 2 Intra-operative procedures

Intra-operative procedures	EVAR (n = 51)	Open repair (n = 71)	P value
IFU	37 (72.5%)		
Zenith	35 (68.6%)		
Excluder	11 (21.6%)		
Power link	4 (7.8%)		
Homemade	1 (2.0%)		
Coiling of IIA	20 (39.2%)		
Large Palmatz	7 (13.7%)		
Tube graft replacement		47 (66.2%)	
Bifurcated graft replacement		24 (33.8%)	
Intra-operative blood loss (ml)	184.5 ± 103.2	252.8 ± 191.5	0.013
Blood transfusion requirement	6 (11.8%)	21 (29.6%)	0.026

IFU: usage within the instruction for use; IIA: internal iliac artery

Table 3 Perioperative outcomes

Preoperative variables	EVAR (n = 51)	Open repair (n = 71)	P value
Operating time (min)	131.4 ± 41.6	155.2 ± 48.6	0.003
Day of discharge (POD)	8.7 ± 4.5	16.4 ± 10.5	0.00
In-hospital mortality	2 (3.9%)	1 (1.4%)	0.571
Cerebral infarction	1 (2.0%)	1 (1.4%)	1.00
Myocardial infarction	0 (0%)	2 (2.8%)	0.509
Ischemic colitis	1 (2.0%)	1 (1.4%)	1.00
Mesenteric infarction	1 (2.0%)	0 (0%)	0.418
Peripheral ischemia	1 (2.0%)	2 (2.8%)	1.00
Wound infection	0 (0%)	2 (2.8%)	0.509

POD: post-operative day

were observed in both groups, however, myocardial infarction and wound infection were only observed in the open surgical repair group, and mesenteric infarction was noted only in the EVAR group. The two patients who developed cerebral infarction had severe atherosclerosis. The symptoms of cerebral infarctions were mild and discharged without symptoms. One octogenarian patient with shaggy aorta required peripheral thromboembol-ectomy after EVAR, finally developed revascularization syndrome and died at 3 post-operative day (POD). The

two patients developed peripheral ischemia after open surgical repair. One patient was treated with thrombec-tomy through the femoral artery, and the other required aorto-femoral bypass with open procedure due to severe iliac multiple stenosis. Mesenteric infarction was occurred in an octogenarian patient with shaggy aorta, and died at 5 POD. In the open surgical repair group, two patients developed perioperative myocardial infarction as a com-plication, one patient died as a result. Both patients who developed myocardial infarction had undergone coronary

artery treatment with drug eluting stents (DES) within 12 months.

The development of endoleaks

Endoleaks are stent graft-specific complications. In the CT examination performed before discharge, no obvious endoleak was found in 40 patients (78.4%), but a Type 1 endoleak was found in two patients (3.9%), a Type 2 endoleak in seven patients (13.7%), and Type 3 endoleak in one patient (2.0%). One patient with type 3 endoleak required reintervention 6 months later. The other endoleaks were disappeared in the following CT investigations.

Discussion

In the EVAR 1 trial, the authors concluded that, compared with open surgical repair, EVAR had a lower perioperative mortality rate, however, required retreatment more often and had a higher associated cost, and did not result in a significant difference in the long-term mortality rate compared with open surgical repair.³⁾ Furthermore, in the EVAR 2 trial, EVAR was performed in patients ineligible for open repair operations, and provided satisfactory results in the perioperative mortality rate, but had no significant difference compared to the long-term mortality rate for patients undergoing medical therapy with follow-up, and about 30% of patients in the EVAR group required retreatment within six years of their operation.⁷⁾ Based on these results, it can be concluded that since open surgical repair does not result in any significant difference in the long-term outcome, eligible patients should undergo open surgical repair from the standpoint of medical economics. However, the mortality rate within 30 days after open surgical repair in the EVAR 1 trial was 4.3%, which was higher than that presently obtained in specialized Japanese facilities.^{5,6)} Our facility conducts interventional treatments including EVAR and open surgical repair for indications such as asymptomatic fusiform aneurysms (>5 cm in diameter), with rapid expansion (faster than 5 mm/6 months), and saccular aneurysms regardless of their size or whether they are symptomatic. Concerning our patient selection, we recommend open surgical repair for low-risk patients. On the other hand, EVAR is undoubtedly recommended for high-risk patients within the instructions for use (IFU). In cases, where high-risk patients outside of the IFU, we discuss the advantage and disadvantage of both treatments in considerable detail with the patients, and

the decision to end it should be entrusted to the patients. We always present a range of therapeutic option, and support the patients' freedom of choice wherever possible. It seems that our indications for interventional treatments do not differ significantly from those at other facilities with respect to aneurysm itself. Furthermore, high-risk patients with preoperative complications are never refused treatment, as per the policy. The present study was performed retrospectively, and preoperative risk factors such as age, cardiac comorbidities, and the history of open surgical repair had a tendency to be higher in the EVAR group. Since the patient backgrounds were different, it cannot be concluded simply based on the present results that open surgical repair is better than EVAR. However, as our facility is a specialized center for aortic aneurysm operations, and open surgical repair is often performed for patients diagnosed as being ineligible for open repair operation at other facilities, relatively high rates of preoperative complications, such as 29.6% of patients with cardiac comorbidities, 28.2% with respiratory comorbidities, and 19.7% with a history of laparotomy were observed. Furthermore, 14.1% of the open repair patients underwent repair of type B aortic dissections, which is generally considered to be difficult to perform, and our facility can be assumed to have patients with backgrounds of higher risk than other facilities. We had only one case of in-hospital death after open surgical repair despite such poor patient backgrounds, which we considered acceptable. In the EVAR group two cases of in-hospital death were observed. Both cases were very complicated octogenarians with huge aneurysms. They were refused both EVAR and conventional surgery because of the heart failure, COPD and shaggy aorta at previous hospitals. Because of their physical conditions, we chose EVAR for them after much debate. However, thromboembolisms were occurred and the results were unfortunate. In patients with shaggy aorta, we re-realized that EVAR should not be chosen without adequate reasons. As stated above, mesenteric infarction and revascularization syndrome after peripheral thromboembolism due to shaggy aorta were the cause of death in the EVAR group. One patient died of perioperative myocardial infarction due to previous DES use in the open surgical repair group. For elderly people being treated DES and having shaggy aorta, which may not be very rare circumstances, in consideration of this retrospective study, there is a limit to be decided to uniformly. Factors such as the degree of shaggy aorta, the type of DES used, and the period since percutaneous coronary

intervention should be considered while making this decision. Therefore, considering all the above factors, these cases require individualized treatment. Accordingly, we concluded that at least low-risk patients who underwent open surgical repair would not have worse perioperative mortality rates or incidences of complications than those undergoing EVAR, and should have a lower probability of retreatment based on conventional data. Therefore, when discussing the issue of which is better, EVAR or open surgical repair, it is important to take into account the characteristics of the facilities where the procedures are being performed as well as the risk factors present in the patients preoperatively and the anatomical problems of the aortic aneurysms themselves. What this means is that it can be reasonably judged that, in facilities with unstable outcomes of open surgical repair, EVAR is a better choice, especially for high-risk patients, while in facilities where open surgical repair obtains good outcomes, taking long-term outcomes into account, open surgical repair is recommended, at least for low-risk patients. We must emphasize that we are not advocating that an open surgical repair is absolutely better, however, believe that giving priority to EVAR treatment often penalizes low-risk patients, thus resulting in a higher cost for the procedure and a higher likelihood of reintervention and endoleaks, without any significant improvement in the long-term mortality rate.

Conclusion

Although, the preoperative patient background showed a tendency toward higher risk in the EVAR group than that of the open surgical repair group, the short-term outcome of the EVAR treatment group in our facility was

satisfactory. In our study, open surgical repairs also showed acceptable outcomes. Presence of shaggy aorta and CAD treated with DES were considerable and important factors for choice of treatments.

Disclosure Statement

The authors have no conflict of interest to disclose with respect to this article.

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