Risk factor analysis of thoracic endovascular repair using the Matsui-Kitamura stent graft for acute aortic emergencies in the descending thoracic aorta

Hiroshi Ohtake, MD,^a Keiichi Kimura, MD,^a Junichirou Sanada, MD,^b Osamu Matsui, MD,^b and Go Watanabe, MD,^a Kanazawa, Ishikawa, Japan

Objective: In recent years, thoracic endovascular aneurysm repair (TEVAR) has been attempted for acute aortic emergencies (AAEs). However, the risk factors for achieving good results have not been identified. Besides focusing on Acute Physiology and Chronic Health Evaluation (APACHE) II score as a general indicator of patient condition, we analyzed both preoperative factors and intraoperative/postoperative factors. The purpose of this study was to identify those factors affecting the results of TEVAR using our Matsui-Kitamura stent graft (MKSG) for AAEs involving descending thoracic aortic aneurysm.

Methods: Between July 2000 and June 2008, a total of 32 patients (23 men, 9 women) with AAEs underwent endovascular repair. AAE was a result of aortic aneurysm rupture in 16 cases, rupture of penetrating atherosclerotic ulcer in 2 cases, traumatic aortic injury in 9 cases, complicated type B dissection in 4 cases, and aortic infiltration of sarcoma in 1 case. Low blood pressure in 6 patients, acute renal failure in 7 patients, anemia due to bleeding in 12 patients were found at the time of operation. Urgent TEVAR using the MKSG was performed. Perioperative and long-term results for these patients were investigated.

Results: The delivery and technical success rate for TEVAR using the MKSG, was 100%. Perioperative mortality was 12.5%, and 5-year survival rate was 71%. In both univariate and multivariate analysis, the APACHE II score clarified a risk factor. Among the various elements of an APACHE II score, age, hematocrit, and total score were identified as significant factors. The mean of an APACHE II score was 9.5. Patients with an APACHE II score \geq 10 showed significantly lower 5-year survival rates than patients with an APACHE II score \leq 9.

Conclusions: Good results were obtained using TEVAR to treat AAEs with MKSGs, both perioperatively and during medium-term follow-up. Evaluation of risk factors for TEVAR of AAEs showed the utility of APACHE II score (particularly age, hematocrit, and total score) with a score ≥ 10 indicating high risk. (J Vasc Surg 2010;52:1464-70.)

Since Dake et al¹ reported the use of thoracic endovascular aortic repair (TEVAR) for the descending thoracic aorta, this procedure has been performed to treat a variety of pathologies of the descending thoracic aorta. This part of the aorta is anatomically easy to approach, and the results of elective TEVAR are good both perioperatively and during long-term follow-up.^{2,3} TEVAR shows a lower incidence of serious postoperative complications such as paraplegia and paralysis than conventional surgery, and has become a trusted method of treatment for descending thoracic artery disorders.^{4,5}

Currently, however, TEVAR is under investigation as a treatment for acute aortic emergencies (AAEs) such as

From the Department of General & Cardiothoracic Surgery,^a and the Department of Radiology,^b Kanazawa University, Kanazawa, Ishikawa, Japan.

0/41-5214/\$30.00

Copyright © 2010 by the Society for Vascular Surgery. doi:10.1016/j.jvs.2010.07.015

1464

aortic aneurysm rupture, aortic dissection, and aortic injury. Despite gradual improvement, conventional surgery is associated with high rates of both mortality and complications.^{6,7} In recent years, TEVAR has been attempted for the treatment of AAEs, albeit on a small number of patients.⁸⁻¹¹ The disorder underlying the AAE can reportedly affect perioperative results,¹² and in addition to the various disorders that can cause an AAE, the overall condition of the patient is also expected to vary greatly depending on the amount of hemorrhage. Numerous factors may be involved in the therapeutic results of TEVAR for AAEs, including preoperative, intraoperative, and even postoperative factors. To assess the general condition of patients at the time of presentation, we used Acute Physiology and Chronic Health Evaluation (APACHE) II score to quantify age, respiration, circulation, blood test findings, Glasgow coma scale, and several chronic diseases. The APACHE II score was proposed by Knaus et al¹³ in 1981 as a severity index for patients admitted to intensive care units and was revised in 1985, and represents a standard indicator of patient status in emergency medicine.

In the present study, TEVAR was performed using the Matsui-Kitamura stent graft (MKSG) that we developed. In Japan, TEVAR was first performed using homemade

Competition of interest: none.

Reprint requests: Hiroshi Ohtake, MD, Department of General & Cardiothoracic Surgery, Kanazawa University, 13-1 Takara-machi, Kanazawa 920-8641, Japan (e-mail: ohtake@med.kanazawa-u.ac.jp).

The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a competition of interest. 0741-5214/\$36.00

Table I. Patient characteristics

Variable	No. or mean ± SD
Age (years)	68.3 ± 14.8
Gender (male:female)	23:9
Smoking	14
Diabetes mellitus	5
History of hypertension	24
Ischemic heart disease	6
Previous aortic surgery	1
Etiology	
Traumatic	9
Rupture of atherosclerotic lesion	18
Aneurysm	16
Penetrating atherosclerotic ulcer	2
Complicated type B dissection	4
Sarcoma invasion	1
APACHE II score	9.5 ± 4.3
Time from onset (hours)	55.9 ± 33.2

APACHE, Acute Physiology and Chronic Health Evaluation.

devices by Kato et al¹⁴ in 1996. In Japan, the TAG (GORE TAG Thoracic Endoprosthesis, W. L. Gore and Associates, Flagstaff, Ariz) became available in 2008 and was followed by the TALENT (Talent Thoracic Stent Graft System, Medtronic Vascular, Santa Rosa, Calif) in 2009. Under these circumstances, we developed the MKSG that has been used in limited Japanese institutions starting from 1999. This flexible stent graft does not apply excessive radial force to the arterial wall and can be loaded into a narrow sheath. We are currently applying the device in clinical settings.^{13,14} The purpose of this study was to elucidate factors affecting the results of TEVAR using our MKSG for AAEs of descending thoracic aortic aneurysms.

MATERIALS AND METHODS

Indications. AAEs of the descending thoracic aorta region are defined as conditions that require emergency treatment, such as aortic aneurysm rupture, aortic injury, and aortic dissection.¹⁵ Patients eligible for TEVAR have a proximal landing zone of ≥ 20 mm at the site where the stent graft will be deployed in the aorta, including the origin of the left subclavian artery, and a distal landing zone of ≥ 20 mm, as confirmed by preoperative computed tomography (CT).

Patient characteristics. Between July 2000 and June 2008, a total of 32 patients (23 men, 9 women) with AAEs underwent endovascular repair. The present study included patients with such symptoms as chest pain, lower back pain, or shock, but did not include asymptomatic patients who were diagnosed by diagnostic imaging. The 32 patients constituted all patients who met the indications during this period. Baseline characteristics of patients are given in Table I. Mean age of the patients was 68.3 ± 14.8 years (range, 33-87 years). An AAE was a result of aortic aneurysm rupture in 16 cases, rupture of penetrating atherosclerotic ulcer (PAU) in 2 cases, traumatic aortic injury in 9 cases, complicated type B dissection in 4 cases, and massive

hemoptysis by aortic infiltration of sarcoma in 1 case. Table II shows each element of the preoperative APACHE II score.

Endovascular repair. All patients routinely underwent a pre-procedural, contrast-enhanced CT scan. Endovascular repair was performed as swiftly as possible after admission to the hospital. All procedures were performed under the permission of Kanazawa University medical ethics committee, and after written informed consent was obtained from each patient.

Stent graft system. The stent graft that we used was developed at our institution and has been used in clinical settings since 1998. The use of this stent graft requires approval from the ethical review board of each institution. We have already reported on the structure of the MKSG and initial clinical experiences in detail (Fig).^{16,17} The MKSG is made from a single 0.30-mm to 0.40-mm diameter nitinol wire (Memoalloy; Tokin, Tokyo, Japan) and comprises a braided framework constructed from a single wire. This framework allows expansion and contraction in relation to aortic diameter, preventing excessive radial force from being applied to areas with a small diameter.

The MKSG was covered with a woven graft made of polyester fabric, then attached with 5-0 interrupted polypropylene sutures. To suit differing curvatures of the aorta, a straight MKSG and a curved MKSG that bends in a right angle have been made. MKSGs ≤36 mm in diameter were deployed through an 18F J-shaped sheath (curved Keller-Timmermans introducer sheath; Cook Diagnostic and Interventional Products, Bloomington, Ind). Larger devices (≤42 mm in diameter) required a 20F sheath. A specially designed preloader-type introducer (Medikit, Tokyo, Japan) was also used to load the device into the sheath. With regard to stent graft selection, the diameter of the stent graft was set to 120% of the proximal site landing zone, and a curved stent graft was selected when the proximal site landing zone was the aortic arch or proximal descending aorta.

MKSGs were selected to exclude the aneurysm completely in cases of aortic aneurysm, to cover the rupture site completely in cases of PAU, to cover the tear completely in cases of traumatic aortic injury, and to cover the entry completely in cases of acute type B dissection. In addition, grafts were selected at sufficient length to ensure a 20-mm landing zone on both proximal and distal sides. In patients with a short proximal landing zone, MKSGs were used in the expectation of sacrificing the left subclavian artery.

Procedures. Stent graft placements were performed in an operating room with the patient under local or general anesthesia and active coagulation time was maintained at 200 to 250 seconds.

After surgical exposure of the common femoral artery, a 5F sheath (Medikit) was inserted into the femoral artery. A 0.032-inch guidewire (Terumo, Tokyo, Japan) was introduced and advanced across the aneurysm into the ascending aorta. The 5F angiographic catheter with calibrated markers was then placed over the guidewire for aortography. After confirming the relationship between the

Elements	Score 0	Score 1	Score 2	Score 3	Score 4	Score 5	Score 6	Mean ± SD
Age in years	3	1	0	6	0	11	11	4.38 ± 1.91
History of severe organ insufficiency								
or immunocompromised	27		_	_		5		0.78 ± 1.84
Rectal temperature (Celsius)	25	7	0	0	0			0.22 ± 0.42
Mean arterial pressure (mm Hg)	26	1	5	0	0			0.50 ± 1.05
Heart rate (ventricular response)	26	2	4	0	0			0.31 ± 0.69
Respiratory rate	23	11	0	0	0			0.34 ± 0.48
Oxygenation	24	4	1	1	2			0.53 ± 1.14
Arterial pH	25	3	3	0	1	_	_	0.41 ± 0.91
Serum sodium	30	1	1	0	0			0.09 ± 0.39
Serum potassium	31	0	0	1	0			0.09 ± 0.53
Serum creatinine	25	3	1	2	1	_	_	0.47 ± 1.05
Hematocrit	20	1	10	1	0	_	_	0.75 ± 1.02
White blood cell count	30	2	0	0	0			0.06 ± 0.25
15-Glasgow coma scale	21	6	3	2	0			0.56 ± 0.91
Total								9.50 ± 4.27

Table II. Each element of the preoperative APACHE II score

APACHE, Acute Physiology and Chronic Health Evaluation.



Fig. The Matsui-Kitamura stent graft.

aneurysm and major branches of the aorta, and determining the best working projection, a 0.035-inch Amplatz stiff guidewire (Cook Diagnostic and Interventional Products) was introduced into the ascending aorta. Transverse arteriotomy of the common femoral artery was performed, and the delivery system was advanced into the target segment of the aorta over the guidewire. Before deployment of the stent graft, the systolic blood pressure was lowered to 90 mm Hg to prevent inadvertent downstream displacement of the stent graft during delivery. The MKSG was deployed under road-mapping guidance, immediately followed by dilation with a large occlusion balloon (Boston Scientific/ Medi-tech, Natick, Mass). To check for adequate stent graft expansion, postprocedural intravascular ultrasound scan was used in all patients.

Follow-up. All patients were subjected to a strict follow-up protocol. Whenever the bare segment of the stent graft covered the orifice of the arch branches, antiplatelet medication was administered from 10 days postop-

eratively. Clinical examination and imaging of the aorta by contrast-enhanced CT were performed, and the diameter of the aneurysm was measured before discharge, at 3-month, 6-month, and 12-month follow-ups, and then annually thereafter.

Definitions and statistical analysis. Technical success was defined as technically successful deployment of the stent graft at the intended target location. All statistical analyses were performed using SPSS software (version 16.0; SPSS, Chicago, Ill). Continuous variables are presented as mean ± 1 SD and range or median and range, and categorical variables are given as frequencies and percentages. Between the survival and aneurysm-related death groups, clinical risk factors were subjected to univariate analysis. Furthermore, Cox regression analysis was performed for these factors. Between the survival and aneurysm-related death groups, each element of APACHE II scores was subjected to univariate analysis. Kaplan-Meier non-parametric methods were used to generate estimates of survival. Kaplan-Meier survival estimates using the log-rank test were used to compare patients with high APACHE II scores (≥ 10) and patients with low APACHE scores (≤ 9). Values of *P* < .05 were considered statistically significant.

RESULTS

Procedural and perioperative results. Procedural data are given in Table III. There were no intraoperative deaths. Delivery and technical success were achieved in all patients. Mean operating time was 106 minutes. MKSGs with an average diameter of 32.4 mm and mean length of coverage of 109 mm were deployed. An 18F or 20F sheath was used in 84% and 16% of patients, respectively. No injury or endoleaks involving the access route were observed. The left subclavian artery was sacrificed in 3 patients. Perioperative mortality was 12.5% (5 aneurysm-related death cases). These 5 patients died perioperatively, comprising 2 cases by re-rupture, 2 cases by respiratory failure, and 1 case of death

Table III. Procedural data

Anesthesia	
Local	15
General	17
Access route	
Via femoral artery	31
Via the conduit of the aorta	1
Simultaneous surgery	
Axillo-axillary bypass	3
AAA surgery	1
MKSG	
Size of the sheath (18F:20F)	27:5
Straight vs curved	12:15
Diameter (mm)	32.1 ± 2.5
Covered length (mm)	118 ± 21.5
Mean operation time (minutes)	106.1 ± 39.6
Amount of blood transfusion (mL)	487.5 ± 209.1
Perioperative mortality and complications	
Mortality	
Re-rupture	2
Respiratory failure	2
Unknown	1
Complications	
Access route injury	0
Surgical conversion	0
Intimal injury	0
Major endoleaks	0
Neurological	
Minor stroke	3
Paraplegia	0
Paralysis	0
Renal failure	1
Long-term ventilation	1

AAA, Abdominal aortic aneurysm; MKSG, Matsui-Kitamura stent graft; min., minutes.

after discharge from the hospital for which the details are unknown. A postmortem examination was performed on 1 patient, showing hemorrhage in the left pleural cavity, but no clear MKSG migration, and no aortic damage.

Mid-term and long-term outcomes. During a median follow-up of 30.8 months (range, 0-102 months), all stent grafts remained patent without evidence of migration, twisting, or fracture. No more aneurysm-related death cases occurred during the following period. Complete embolization of aneurysms was achieved in all patients other than the 5 who died during the perioperative period. The only case in which additional stent graft insertion was required was the patient with sarcoma, in whom re-intervention was performed after 3 months to treat infiltration of the sarcoma into the aorta. Overall survival rates were $78.1 \pm 0.7\%$ at 1 year, $78.1 \pm 0.7\%$ at 3 years, and $71.0 \pm$ 9.5% at 5 years. Deaths during long-term follow-up comprised 1 case each of death due to heart failure, respiratory failure, cerebral infarction, and cancer.

Risk factor analysis. The univariate risk factor analysis showed that preoperative ischemic heart disease and an APACHE II score were significant risk factors (P < .05; Table IV). Of the various elements of APACHE II score, age, hematocrit, and total score were risk factors (Table V). Cox regression analysis showed that only an APACHE II score was a risk factor (Table VI). The mean of APACHE II score was 9.5. When we categorized patients into 2 groups according to APACHE II score (≥ 10 vs ≤ 9), a significant difference (P = .037) in the survival rate was seen between patients with postoperative intimal injury and those without (94.4 \pm 5.4% vs 57.1 \pm 13.2% at 1 year, 94.4 \pm 5.4% vs 57.1 \pm 13.2% at 3 years, and 78.7 \pm 15.1% vs 57.1 \pm 13.2% at 5 years; P < .05).

DISCUSSION

In the present study, perioperative mortality and 5-year survival rates for TEVAR using the MKSG for AAE were 12.5% and 71%, respectively. These results were compatible to those in previous reports of TEVAR for AAE.9,18 In particular, delivery was possible using a narrow sheath (20F or narrower, 18F in 84%), and the absence of access route damage was a major advantage of the MKSG system. In both univariate and multivariate analyses, an APACHE II score was clarified as a risk factor. APACHE II score analyses showed that age and low hematocrit due to hemorrhage are risk factors. In addition, with regard to long-term survival, the results suggest that an APACHE II score is the only significant risk factor and is a predictor of outcomes. Mean APACHE II score was 9.5, and patients with a score \geq 10 showed a significantly lower 5-year survival rate than those with a score ≤ 9 , so a score ≥ 10 was regarded as indicating high risk. None of the underlying disorders constituted a significant risk factor, but atherosclerotic disorders tended to show much higher risk than traumatic aortic injury, suggesting that rupture of an aortic aneurysm or PAU may be more serious.

The use of TEVAR for AAEs, including appropriate indications, remains a challenging field, and few reports have described around 30 cases compared with reports of open surgery.^{9,18} We also began stent graft insertion for thoracic aortic aneurysms in the year 2000 and have clinical experience with approximately 200 patients, but these include only 32 cases of AAEs. We established solely anatomical conditions for treatment indications that patients should have: a proximal landing zone ≥ 20 mm, including the origin of the left subclavian artery; and a distal landing zone ≥ 20 mm. We chose to perform open surgery on patients in whom a sufficient landing zone could not be ensured. These conditions were the same as those for non-AAE descending aortic aneurysms in terms of both landing zone and MKSG diameter.^{16,17} Three sudden deaths were observed during the perioperative period, and type I endoleaks (endoleaks that could have been prevented with a longer landing zone) could not be definitively ruled out. However, with TEVAR, a longer landing zone is ideal, and the landing zone should be as long as possible in the treatment of an AAE.

Both delivery and technical success rates were 100%. Neither a type I nor type II endoleak was observed in any patient during intraoperative angiography. The main cause of failure in the use of TEVAR for AAE is damage to the access route caused by the device,¹⁹ which reportedly occurs in 3% to 15% of patients.^{18,20} This is due to factors such as aortic collapse because the patient is in shock, or the

Clinical risk factor	Survival group (n = 27)	Procedure-related death group $(n = 5)$	P value
Categorical data			
Gender (male:female)	19:8	4:1	.66
Smoking	11	3	.43
Diabetes mellitus	4	1	.77
Hypertension	19	5	.16
IHD	3	3	.01
CVD	2	0	.53
Non-thoracic trauma	5	0	.30
Underlying disorder			
Trauma	9	0	
Atherosclerotic lesion	13	5	
Complicated type B dissection	4	0	
Tumor	1	0	
Postoperative complications	5	0	.30
Non-categorical data			
Time from onset (hours)	28.3 ± 33.2	31.6 ± 36.9	.84
APACHE II score	8.4 ± 3.2	16.0 ± 3.9	.00
Operation time (minutes)	97.4 ± 32.6	134.0 ± 62.0	.06
Blood transfusion (mL)	481.5 ± 216.7	520.0 ± 178.9	.71
Length of coverage by MKSG (cm)	120.5 ± 28.3	106.0 ± 16.0	.28

Table IV. Univariate analysis of clinical risk factors

APACHE, Acute Physiology and Chronic Health Evaluation; CVD, cerebrovascular disease; h, hours; IHD, ischemic heart disease; min., minutes; MKSG, Matsui-Kitamura stent graft.

Table V.	. Univariate ar	alysis of	each elen	nent of the
preopera	tive APACHE	II score		

Elements	Survival group (n = 27)	Procedure- related death group (n = 5)	P value
Age in years	4.15 ± 2.00	5.60 ± 0.55	.00
History of severe organ insufficiency or			
immunocompromised	0.74 ± 1.81	1.00 ± 2.24	.78
Rectal temperature	0.19 ± 0.40	0.40 ± 0.55	.30
Mean arterial pressure	0.52 ± 1.09	0.40 ± 0.89	.82
Heart rate	0.26 ± 0.66	0.60 ± 0.89	.32
Respiratory rate	0.37 ± 0.49	0.20 ± 0.45	.48
Oxygenation	0.37 ± 0.97	1.40 ± 1.67	.61
Arterial pH	0.22 ± 0.58	1.40 ± 1.67	.19
Serum sodium	0.11 ± 0.42	0.00 ± 0.00	.57
Serum potassium	0.00 ± 0.00	0.60 ± 1.34	.37
Serum creatinine	0.33 ± 1.00	1.20 ± 1.10	.09
Hematocrit	0.56 ± 0.89	1.80 ± 1.10	.01
White blood cell count	0.04 ± 0.89	0.20 ± 0.45	.47
15-Glasgow coma scale	0.44 ± 0.89	1.20 ± 0.84	.09
Total	8.30 ± 3.12	16.00 ± 3.94	.00

APACHE, Acute Physiology and Chronic Health Evaluation.

additional presence of serious atherosclerosis in peripheral arteries in atherosclerotic disorders. We have developed the MKSG, a stent graft of up to 36 mm in diameter capable of delivery at 18F, and achieved safe delivery in all cases in the present series with no damage to the access route via a femoral artery approach. In addition, no intraoperative aortic injury was seen in the neighborhood of the rupture site, and no complications caused by the procedure were observed. The use of a range of different devices has been reported, but the MKSG, which can be fitted with a smaller size sheath, is regarded as useful for AAEs.

To minimize perioperative complications, we were careful to maintain optimum blood pressure during surgery as protection for the spinal cord. Active coagulation time was set at a maximum of 180 to 200 seconds to prevent hemorrhage as much as possible, and some patients were not administered heparin. Fortunately, neurological complications of paraplegia and paralysis did not occur in this series. Cerebrospinal fluid drainage is not easy to perform for the patient in shock, so maintaining blood pressure may be even more important. In addition, re-intervention was not performed in any patient other than a single case in which the aneurysm diameter increased due to cancer growth during long-term follow-up, and no device-related complications were encountered during the observation period. However, late complications are said to increase beyond 5 years postoperatively, and we intend to continue careful observation using CT scans in the future.

Disorders that can cause AAEs include aortic injury, aortic rupture, and acute or chronic dissection. The perioperative mortality of TEVAR for AAEs resulting from aortic injury has been reported as around 2%.¹⁰ Rates of around 10% for a ortic rupture^{21,22} and around 15% for type B dissection²¹ have been described somewhat higher than the rate for aortic injury. In the present study, however, the only risk factor found was an APACHE II score on hospital arrival, with patients showing scores ≥ 10 having significantly worse prognosis. An APACHE II score is widely used in emergency medicine and intensive care as an index for determining the patient's general condition, including age and underlying disorder.¹³ As all disorders caused by AAEs result in a swift deterioration in patient conditions as a result of hemorrhage, overall assessment of the general condition on arrival at the hospital can be expected to

Factor	No. or mean value	Significance	Hazard ratio	(95% CI)
Categorical data				
Sex (male:female)	23:9	0.677	5.090	0.002-10815.843
Smoking	17	0.515	0.312	0.009-10.394
Diabetes mellitus	4	0.275	9.554	0.166-549.356
Hypertension	24	0.676	0.272	0.001-121.583
IHD	6	0.444	0.245	0.007-8.977
CVD	2	0.882	0.000	0.000-3.995E51
Non-thoracic trauma	16	0.830	4922.53	0.000-2.825E37
Underlying disorder				
Trauma	9	0.975	0.008	0.000-3.297E129
Atherosclerotic lesion	18	0.969	329.077	0.000-4.818E129
Complicated type B dissection	4	0.992	0.202	0.000-2.176E132
Tumor	1			
Postoperative complications	4	0.909	0.009	0.000-5.456E32
Non-categorical data				
Time from onset (hours)	28.8	0.978	0.999	0.949-1.052
APACHE II score	9.6	0.046	1.948	1.013-3.743
Operation time (minutes)	103.1	0.990	1.000	0.990-1.035
Blood transfusion (mL)	487.5	0.999	1.000	0.000-1.010
Length of coverage by MKSG (cm)	118.2	0.229	0.905	0.770-1.065

Table VI. Cox regression analysis of clinical risk factors

APACHE, Acute Physiology and Chronic Health Evaluation; CI, confidence interval; CVD, cerebrovascular disease; hrs., hours; IHD, ischemic heart disease; min., minutes; MKSG, Matsui-Kitamura stent graft.

correlate with prognosis. Furthermore, an APACHE II score factor analysis clarified age, hematocrit, and total score as risk factors. In this study, the time between onset and hospital arrival was not identified as a risk factor. This was regarded as being influenced by the fact that some patients were under observation at a community hospital because their hemodynamic status was stable. We believe that an important treatment strategy for minimizing the number of high-risk patients with scores ≥ 10 is to prevent general conditions from deteriorating between AAE onset and arrival at a hospital by performing stent graft insertion as swiftly as possible.

Limitations. The present study was limited by the relatively low number of patients treated. As a result, no definitive predictors could be identified. Because the MKSG that we developed is not a commercially available device, use of the device at institutions other than our own is currently difficult. In addition, this was not a randomized controlled trial. Instead, we reported our mid-term experience with a median follow-up of 30.8 months. Long-term follow-up studies are necessary to assess the durability and effectiveness of TEVAR for AAEs. Causes of perioperative mortality were sudden death, multiple organ failure, and respiratory failure. Determination of a final judgment as to whether the sudden deaths were caused by the general condition of the patient or developed as a result of TEVAR technical failure was not possible. In the 2 patients for whom thoracic radiographs and CT scans could be obtained, no major migration of the MKSG or dissection was observed. In the future, therapeutic results should be improved by more detailed analysis of the causes of perioperative death.

CONCLUSIONS

Good results were obtained using TEVAR with MKSGs for AAEs, both perioperatively and during medium-term follow-up. The lack of access route damage was a major advantage of the MKSG system. Evaluation of risk factors for TEVAR of AAEs showed the utility of an APACHE II score (particularly age, hematocrit, and total score) with a score ≥ 10 indicating high risk. This study identified an APACHE II score as the only statistically significant risk factor, representing a predictor of outcomes.

The authors gratefully acknowledge the medical and technical assistance of Dr Shigeyuki Tomita, Dr Shoujirou Yamaguchi, and Dr Hiroki Kato of the Department of General & Cardiothoracic Surgery and Dr Tetuya Minami, Dr Kumi Ozaki, and Dr Takahiro Ougi of the Department of Radiology at Kanazawa University. In particular, we would like to thank Prof Hiroyoshi Nakamura and Dr Yuri Hibino of the Department of Environmental and Preventive Medicine at Kanazawa University for their helpful suggestions regarding statistical analysis.

AUTHOR CONTRIBUTIONS

Conception and design: HO, JS, OM, GW Analysis and interpretation: HO, KK, JS Data collection: KK, JS, OM Writing the article: HO, JS Critical revision of the article: HO, JS, KK Final approval of the article: OM, GW Statistical analysis: HO, KK Obtained funding: Not applicable Overall responsibility: HO

REFERENCES

- Dake MD, Kato N, Mitchell RS, Semba CP, Razavi MK, Shimono T, et al. Endovascular stent-graft placement for the treatment of acute aortic dissection. N Engl J Med 1999;340:1546-52.
- Appoo JJ, Moser WG, Fairman RM, Cornelius KF, Pochettino A, Woo EY, et al. Thoracic aortic stent grafting: improving results with newer generation investigational devices. J Thorac Cardiovasc Surg 2006;131: 1087-94.
- Wheatley GH III, Gurbuz AT, Rodriguez-Lopez JA, Ramaiah VG, Olsen D, Williams J, et al. Midterm outcome in 158 consecutive Gore TAG thoracic endoprostheses: single center experience. Ann Thorac Surg 2006;81:1570-7; discussion 1577.
- 4. Adams JD, Angle JF, Matsumoto AH, Peeler BB, Arslan B, Cherry KJ, et al. Endovascular repair of the thoracic aorta in the post-FDA approval era. J Thorac Cardiovasc Surg 2009;137:117-23.
- Ouriel K, Greenberg RK. Endovascular treatment of thoracic aortic aneurysms. J Card Surg 2003;18:455-63.
- Rousseau H, Dambrin C, Marcheix B, Richeux L, Mazerolles M, Cron C, et al. Acute traumatic aortic rupture: a comparison of surgical and stent-graft repair. J Thorac Cardiovasc Surg 2005;129:1050-5.
- Minatoya K, Ogino H, Matsuda H, Sasaki H, Yagihara T, Kitamura S. Replacement of the descending aorta: recent outcomes of open surgery performed with partial cardiopulmonary bypass. J Thorac Cardiovasc Surg 2008;136:431-5.
- Bortone AS, De Cillis E, D'Agostino D, de Luca Tupputi Schinosa L. Endovascular treatment of thoracic aortic disease: four years of experience. Circulation 2004;110(Suppl II):II262-7.
- Pitton MB, Herber S, Schmiedt W, Neufang A, Dorweiler B, Düber C. Long-term follow-up after endovascular treatment of acute aortic emergencies. Cardiovasc Intervent Radiol 2008;31:23-35.
- Xenos ES, Abedi NN, Davenport DL, Minion DJ, Hamdallah O, Sorial EE, et al. Meta-analysis of endovascular vs open repair for traumatic descending thoracic aortic rupture. J Vasc Surg 2008;48:1343-51.
- Ferrari E, Tozzi P, von Segesser L. Thoracic aorta emergencies: is the endovascular treatment the new gold standard? Interact Cardiovasc Thorac Surg 2006;5:730-4.

- Kurimoto Y, Morishita K, Asai Y. Endovascular stent-graft placement for vascular failure of the thoracic aorta. Vasc Health Risk Manag 2006;2:109-16.
- Knaus WA, Draper EA, Wagner DP, Zimmerman JE. APACHE II: a severity of disease classification system. Crit Care Med 1985;13:818-29.
- 14. Kato M, Ohnishi K, Kaneko M, Ueda T, Kishi D, Mizushima T, et al. New graft-implanting method for thoracic aneurysm or dissection with a stented graft. Circulation 1996;94(9 Suppl):II188-93.
- Ahmad F, Cheshire N, Hamady M. Acute aortic syndrome: pathology and therapeutic strategies. Postgrad Med J 2006;82:305-12.
- Sanada J, Matsui O, Terayama N, Kobayashi S, Minami T, Kurozumi M, et al. Clinical application of a curved nitinol stent-graft for thoracic aortic aneurysms. J Endovasc Ther 2003;10:20-8.
- Ohtake H, Kimura K, Watanabe G, Sanada J, Matsui O. Clinical application of an original flexible MK stent-graft for nonruptured thoracic aortic aneurysms: early experience. Innovations 2006;1: 119-22.
- Kaya A, Heijmen RH, Rousseau H, Nienaber CA, Ehrlich M, Amabile P, et al. Emergency treatment of the thoracic aorta: results in 113 consecutive acute patients (the Talent Thoracic Retrospective Registry). Eur J Cardiothorac Surg 2009;35:276-81.
- Makaroun MS, Dillavou ED, Kee ST, Sicard G, Chaikof E, Bavaria J, et al. Endovascular treatment of thoracic aortic aneurysms: results of the phase II multicenter trial of the GORE TAG thoracic endoprosthesis. J Vasc Surg 2005;41:1-9.
- Zipfel B, Hammerschmidt R, Krabatsch T, Buz S, Weng Y, Hetzer R. Stent-grafting of the thoracic aorta by the cardiothoracic surgeon. Ann Thorac Surg 2007;83:441-8; discussion 448-9.
- Milnitchouk S, Pfammatter T, Kadner A, Dave H, Witzke H, Trentz O, et al. Emergency stent-graft placement for hemorrhage control in acute thoracic aortic rupture. Eur J Cardiothorac Surg 2004;25:1032-8.
- Morishita K, Kurimoto Y, Kawaharada N, Fukada J, Hachiro Y, Fujisawa Y, et al. Descending thoracic aortic rupture: role of endovascular stent-grafting. Ann Thorac Surg 2004;78:1630-4.

Submitted Nov 1, 2009; accepted Jul 9, 2010.